HIT Policy Committee Meeting
Final Transcript
June 25, 2010

Presentation

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you very much. Good morning, everybody, and welcome to the 13th meeting of the HIT Policy Committee. This is a federal advisory committee. It's being conducted in public, and there will be opportunity at the close of the meeting for the public to make comment here in the room or on the telephone or via the computer. And the summery of the meeting will be posted on the ONC Web site. Just a reminder for committee members to please identify yourselves for attribution when speaking, and I will go around the room now and have you introduce yourselves starting on my left with Tony Trenkle.

Tony Trenkle – CMS – Director of OESS
I am Tony Trenkle from the Centers for Medicare and Medicaid Services.

Scott White – 1199 SEIU – Assistant Director & Technology Project Director
Good morning. Scott White, 1199 SEIU.

Marc Probst – Intermountain Healthcare – CIO
Marc Probst with Intermountain Healthcare.

Charles Kennedy – WellPoint – VP for Health IT
Charles Kennedy, WellPoint.

Gayle Harrell – Florida – Former State Legislator
Gayle Harrell, former state representative from Florida.

David Bates - Brigham and Women's Hospital - Chief, Div. Internal Medicine
David Bates, Brigham Women's Hospital and Partners Healthcare.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Paul Tang, Palo Alto Medical Foundation.

Art Davidson - Public Health Informatics at Denver Public Health – Director
Art Davidson, Denver Public Health ….

Paul Egerman – eScription – CEO
Paul Egerman, software entrepreneur.

Adam Clark – Lance Armstrong Foundation – Director for Health Policy
Adam Clark, LiveStrong.

Judy Faulkner – Epic Systems – Founder
Judy Faulkner, Epic.

Stephen Ondra – NeHC – Senior Policy Advisor
Steve Ondra, Department of Veterans Affairs.

Judy Sparrow – Office of the National Coordinator – Executive Director
I believe we have a number of committee members on the telephone. Rick Chapman, are you there?

Rick Chapman – Kindred Healthcare – Chief Administrative Officer/CIO/EVP
Yes, I am.

Judy Sparrow – Office of the National Coordinator – Executive Director
Jim Borland?

Jim Borland – SSA – Special Advisor for Health IT, Office of the Commissioner
Yes, Judy. I'm here. Thank you.

Judy Sparrow – Office of the National Coordinator – Executive Director
Deven McGraw?

Harley Geiger – Center for Democracy & Technology – Staff Counsel
Deven's flight to D.C. was cancelled last night. I'm Harley Geiger from CDC, and I'll be taking notes on her behalf.

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you, Harley. Connie Delaney?

Connie Delaney – University of Minnesota School of Nursing – Dean
Present.

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you. Anyone else on the telephone line?

Neil Calman - Institute for Family Health - President & Cofounder
Yes, Neil Calman. I'm here.

Judy Sparrow – Office of the National Coordinator – Executive Director
Right, Neil. Sorry. Thank you, Neil. I'll turn it over now to Paul Tang.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
We'll give David a little chance to catch his breath here. Welcome, everyone, and we have a packed agenda, but we're doing a little time shifting because there are a number of members who have to leave early. Let me go over the revised agenda, and see if that will work for everybody. We're going to start out with, as soon as I get done here, then David Blumenthal will give his opening remarks.

We'll then go into a discussion of NHIN, both NHIN Direct, sort of the starter set for health information exchange and the NHIN, and then be introduced to NHIN governance discussion that Mary Jo Deering will conduct, and that'll be from 10:30 to 11:30. Then George Hripcsak is going to talk about the meaningful use workgroup hearing on disparities. He'll give us an update on that at 11:30.

Then at 11:45, Paul Egerman will discuss, in Deven's absence because her flight was cancelled, will discuss the privacy and security tiger team, which I used to think was a fast animal. I just got from an African safari and met up with some cheetahs who can go 60 miles and hour, so I think we might need to invent the cheetahs later on if necessary. That'll be a discussion for an hour until 12:45 when we'll break

for lunch until 1:15 when Aneesh Chopra will talk to us about the enrollment workgroup that's new and that started up at our last meeting.

Then Steve Posnack and Carol Bean will talk to us about the newly released temporary certification rule, and we'll close, we'll start the public comments approximately at 2:00 p.m., so we'll finish by no later than 2:30 anyway. That's the revised schedule to try to accommodate various people's travel schedules. Any issues with that? Great. Thanks. One more piece of business: You all received the minutes from the last meeting, and I'll entertain any motions for approval or comments.

W
Move approval.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Second?

M
Second.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
All in favor?

W
Aye.

M
Aye.

M
Aye.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Any opposed, and any abstentions? I'll turn it back over to Dr. Blumenthal then for his opening remarks.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Welcome. Sorry to be late. A lot of important material on the agenda today, and we're sort of in a period of winding up the first set of meaningful use standards and certification work, and then looking ahead to the next phase of the same. But in the meantime, we have all kinds of continuing issues that we need to pay attention to, the continuing work on privacy and security, the preparation for a possible rule on governance of the NHIN, which we were tasked by the Congress with thinking about, and then continuing to work on the substrate for interoperability in our health system through the National Health Information Network and its standards and policies and implementation specifications.

There's no end to the specific issues that we need your help with and grateful that you continue to come into these meetings and give us your opinions as generously as you do. I think the most important for a Friday meeting is to get to the agenda as quickly as possible, so I'm going to keep my comments short and turn the microphone back to Paul and invite our first panelists who are patiently waiting in front of us, Mary Jo Deering and Doug Fridsma.

Doug Fridsma – Arizona State – Assoc. Prof. Dept. Biomedical Informatics

Thank you, David. Everybody should have included in their packet a list of all the slides for today. There are about 19 slides. I'm going to go through about six of them. We're going to try to accelerate the schedule, and that will give the other slides that are in the pack, we will use as reference materials, and obviously if there are specific questions that come up, I'm happy to answer those as well.

As a matter of framing, I want to sort of think about standards and standards development and give this particular committee some insight, at least at a high level because, as we think about governance, and as we think about the coordination that's necessary, there are policy implications, and there are things that we need your advice on. And so I want you to understand sort of the ecosystem in which we see the standards being developed and then open it up for questions.

One of the things that we've been working on very hard within the Office of the National Coordinator is trying to support the lifecycle of standards and interoperability. If we think about this, there are meaningful use criteria that this committee will establish, and there will be, as a result of that, standards that will be recognized by the standards committee and then implemented in technology and used for certification criteria. But there's a whole bunch of stuff that has to happen between the time that you have a policy recommendation and that those standards are constructed. I think this committee understands the policy work ahead of you with regard to meaningful use and the coordination that's necessary with the standards committee and the work that goes on with the certification process. But I hope that at the end of this sort of brief talk and going through some of the slides on your own, you'll have a sense for some of the things that have to happen in between and where there might be needs for us to be able to have coordination, both within policy and within standards about how we do our work.

In setting up the standards and interoperability framework, one of the things that we're really trying to do is create more computational implementation specifications, and so an implementation specification is a recipe. It tells people how to build software to do certain things. So if there are meaningful use criteria that you guys have established, those have to be translated into recipes that people can sort of follow to be able to meet that in the software that they develop. We can write those in big paragraphs, but it leaves a lot of room for people to have interpretation.

One of the things that we're trying to do is to make it easier for folks to be able to actually achieve the goals of meaningful use by having recipes that are reproducible and that, at the end of the day, produce the same kind of cake, if you will, and that we don't have lots of flavors that don't necessarily work together. We also want to be able to develop tools that increase the efficiency of our ability to develop standards and implementation specifications, these recipes, and to do that, we have to have computational ways of doing that. It's easier for us to manipulate things that are in models that computers can understand than it is for us to have big paragraph descriptions of what goes on.

What we're also trying to do in the standards and interoperability framework is to link the use cases or the things that we have, the problems that we're trying to solve with meaningful use policy objectives all the way from the work that you guys are doing on the policy committee all the way through to the standards that get adopted and the certification criteria. We want to make sure that there's not a break in that chain all the way through, and that we can have traceabilility that says we've got the technology with certification criteria that traces all the way back to the goals and objectives of the policy committee. So we want to keep that process tightly linked. We're working very closely with NIST to make sure that they're involved in this process.

Again, if we have very, very specific requirements that come from policy and are translated into these recipes, we can then develop tools for certification that will make it easier for companies and organizations to certify against those criteria. So what we can do then is we develop testing for

compliance at the same time that we develop the standards and interoperability specifications, and that allows us to sort of tightly link those things together. So at the end, we're not testing against things that are not representative of sort of the policy objectives of the committee.

Also, I think, as you know, there are a lot of different standards development organizations and different standards that are needed to achieve the policy objectives. So to be able to send a clinical summary record, we need to have standards from HL-7. We need standards from ICD-9. We need standards from SNOMED. There's a whole series of different standards that need to come together, and so we have to have an ability to take all of those standards, integrate them into a package, and have that implementation specification or recipe out there for people to use.

Part of what we're trying to do is we want to make sure that we can use this interoperability framework to address whatever kind of specification and standards that might come down the pike. And so if we think about some of the NHIN Direct activities and, at the end of this presentation, I'm going to ask Arien, who is on the phone, to speak a bit about the NHIN Direct project. But what we hope to be able to do is to take things like NHIN Direct and interoperability framework, put those together, and provide focused collaboration to achieve our objectives.

There's a tension always with trying to create standards and interoperability specifications where you'd like to have somebody at the top say this is how you will do it, kind of a command and control, which is a good way to get everybody to kind of march in line, but it's not a good way to drive innovation and to drive a marketplace. At the other side, it's 1,000 flowers bloom. We let everybody sort of do what they think they need to do to sort of achieve those objectives, but we complicate our life, and we make it harder for us to get to that interoperability objective that we've got.

So what we're hoping to be able to do, and what we hope this interoperability framework will allow us to do, is to do bottom up, innovative solutions to try to solve interoperability problems and to address some of the policy directives that we get from this committee, but to do it within a framework that helps coordinate among the different activities and the standards development efforts so that we do, at the end of the day, all come out at the end with similar sets of standards, implementation specifications, and goals. And we've been following a lot of the core principles that have come from the implementation working group to try to make sure that we have transparency, engagement, rapid results. Don't try to boil the ocean. Try to be able to be responsive to needs that are out there as well.

I have a whole series of slides, but I'm going to stop at this slide and then go to the end and just step through the boxes that we have in this interoperability framework. One of the things that will happen is that, I guess it's on my left side, depending on where you guys are, I guess it's your left or right, but is that we expect that the policy committee will come up with use cases that will say we would like for meaningful use, for people to have the following ability, that they can do certain functions. That might be electronic prescribing. It could be the exchange of this clinical summary record. But those kinds of recommendations will come from the policy committee. We may have recommendations that will come from other agencies that are working on high visibility projects such as VELOR or other activities. And those things will come and be described as use cases and functional requirements.

That first step is taking the paragraph description of the goal that you want to accomplish and decomposing it into the data that you need to do and the functions that you need to perform to be able to accomplish that use case. So for example, electronic prescribing, we would have to then say we need to have electronic prescription capabilities within an electronic health record, and there needs to be the ability to transmit that or send that, so that's a function that needs to be described. But there's data as well.

We need to be able to describe the electronic prescription. We need to be able to sort of populate that with the important elements that we have. We may need to have some notion of acknowledgement.

There may be something that if I send it, I have to know that it has been properly received. And so part of the use case development and functional requirements is taking that paragraph description and breaking it down into its data that's required, if there are particular services or functions that are required, and then if there are policy implications, again, having those sort of articulated as well. Those things will then go into what we call a kind of harmonization of core concepts.

Now we are going to be using something called the NIEM framework, which is the National Information Exchange Model. There are some slides that are in there. This is a process that we are going to adopt that will help us whenever two use cases come in and they have the same thing like a patient. We want to make sure that the patient that we describe for electronic prescribing has the same kind of data elements and the same sort of functions that it needs to be participating in, as say a patient around a clinical summary.

If we describe name or if we describe identifier or if we describe other attributes of that patient differently across different use cases, it becomes hard for us to be able to have sort of a comprehensive view of the standards that are out there. So we take those paragraph descriptions. We break them down into their elements, the data that needs to be done and the activities we have to perform, and then we make sure that those are harmonized, that we don't have duplication, that we don't have conflicts, and that we try to make sure that all of those pieces can function together.

Once we've done that, we can then describe an implementation specification. So if you think about those core concepts as being ingredients, the implementation specifications takes those ingredients and assembles them into a recipe. And the implementation specification will say here are the data elements that you need to be able to do electronic prescribing. Here are the standards that you need, so you may need to be using NCPDP as a transport mechanism. And you might need to be using a vocabulary that maps to RxNorm as one of the terminologies that you would use. And it might describe something about the functions. You need to be able to send that, and you need to be able to receive it and the like.

And so the implementation specifications are that recipe that then we can use to describe the functionality that we need both for certification and if somebody wants to build that software. It's important that we don't do this in the abstract as well. I mean, there are many examples that we can point to of implementation specifications created in committee meetings that all seem very good on paper, but the devil is in the details when you get out there and try to build the software. And so as part of a quality check for those implementation specifications, we need to do reference implementations.

We need to actually build it. We have to bake the cake, if you will. We have to have a test kitchen that makes sure that the recipe is correct. And so we have work within this interoperability framework to take those specifications, develop reference implementations, and then use that to demonstrate in kind of pilot projects. And so that will give us both real world experience to make sure that those implementation specifications are correct.

The final piece of this is certification and testing, and if we have reference implementations that can be constructed, for example, to exchange electronic prescriptions, we can use those reference implementations as one end of the interoperability connection so that NIST and others can develop tools that say I'm going to send an electronic prescription, and if it can be received correctly by our reference implementation, there's a good chance you're following our standards or our recipe correctly. And

underlying all of this are going to be tools and services because, at the end of the day, this needs to be something that is not, you know, I'm in the standards business, so I like to standardize the standards as well. And so that means that we need tools and services that makes this possible for other people to be able to develop their use cases that we can do it more efficiently because we don't start with a blank sheet of paper, but we have the ability to sort of pull down existing use cases and say what I need to do for laboratory transmission reuses some of the services that are similar to what I'd have to do to send an electronic prescription.

There's sort of a transmission requirement with that. And that includes work with vocabulary browsers, being able to set up value sets, which are the elements that will populate. A value set example would be if you had problem lists, maybe there's a shortened list of problem lists that we might need to develop that will make it easier for implementation, and so we're developing tools and services that I think will integrate across this lifecycle.

The thing I think that I hope will happen is as we go from 2011 to 2013 to 2015, we'll develop within this interoperability framework the ability to have an ecosystem in which pilot demonstration projects will feed back in to our use cases and say we need to extend this or change it or modify it. We'll get advice from the policy committee here about use cases and things we should work on. And we can feed back and tell you based on this process what was easy for us to implement and what was hard and what things worked in the real world and what things didn't based on those implementation specifications. But at the end of the day, we want to have this ecosystem that will allow us to manage the lifecycle all the way from the work that you're doing here on the committee around policies and objectives all the way down to what gets implemented.

I'm going to quickly skip all the way to the end. Everybody can look at all that other stuff. We've got a whole bunch of artifacts that we will be developing. Next week, I'll be presenting to the standards committee a much more detailed review of this process that is our concept of operations that we'll talk very specifically about the kinds of milestones and decision points that are needed throughout this that I think we need to engage and let the standards committee sort of know how we might be working on that.

But I think the thing that's important and the reason that I wanted to kind of give you this overview is one of the first use cases that we are going to put through this interoperability framework is the NHIN Direct project. And so what's important is to recognize that NHIN Direct as a project, the activities, if you take a look at what we've articulated in the standards and interoperability framework, we're doing a lot of these activities. We've got pilot demonstration projects out there that are trying to develop reference implementation. They're trying to develop some of the implementation specifications as well. And we're working very closely with the teams to make sure that those use cases and storyboards that are happening on the NHIN Direct Web site are being translated into the concepts that we need within this particular framework as our first pilot through because NHIN Direct, it's critical, it's part of this larger ecosystem, and part of sort of our goal of having a comprehensive and harmonized set of specifications that can support interoperability.

I don't know if Arien is on the phone. I have now the last slide up, which is the NHIN Direct example that talks a little bit about the boxes that we have within the interoperability framework, how those things map into the NHIN Direct activities, how they work within the S&I framework activities, and how the HIT Policy Committee activities are also working together with them. With that, if Arien is on the phone, I'll turn it over to him and have him step through the NHIN Direct example slide. Do we know if he's on the phone?

M
He's logged into the Web interface, but he may not be.

Doug Fridsma – Arizona State – Assoc. Prof. Dept. Biomedical Informatics

He may not be. Well, while you guys work that out, I will channel Arien and see if I can speak to his slides that he developed. What we have across the top is the first letter of every month, and so we've got June, July, August, September, October, November, December, and then going on from there. And so this is sort of the timeframe of what we expect to be happening within the NHIN Direct project. In June and July, they are going to be developing or sort of identifying those implementation specifications that they would like to go forward with, and there are a number of different architectural and different standards that they're looking at with regard to this. There is, I think, the beginning of consensus about which of those that they should follow through.

The three principal contenders are an SMTP or an e-mail based approach of exchanging information that has security and encryption as an important part of the package. There is a SOAP based approach, which is sort of – it stands for service-oriented architecture. It's very similar to what currently exists within the NHIN software specifications and the work that's going on with the Connect project. Then there's also one that's called West, and that really is something that is based on Web-based interfaces and HTTP and Web services and the like.

But those implementation specifications, as they sort of converge on the one set they want to explore, will then develop some reference implementations and do some pilot testing for us. Again, trying to make sure that we've tested out the implementation specifications before we lock them down or decide that this is the way forward. In parallel to that, the team that we have within the ONC is taking those implementation specifications and those use cases and translating them into these NIEM artifacts. So translating them into the computational pictures that we need to be able to look at to be able to then use the tools at our disposal to harmonize and to integrate the, and to come up with kind of a unified view of how the standards and the interoperability requirements work together.

In parallel to that, and in kind of close collaboration, we have the policy committee and the tiger team on policy that's trying to take a look at privacy and security to make sure that they can, in parallel, evaluate the specifications that are coming out of the NHIN Direct project and making sure that those are consistent with the policies that we have within this particular tiger team. Then there's also going to be a specification and policy review. We anticipate having a joint team between policy and standards that will then look at those specifications and, again, provide a way for us to review and examine those specifications, making sure that they meet the policy objectives o this committee, and that they have the kinds of standards that the standards committee would like to have within that.

We anticipate that come the first part of next year, the formal review, we will have had some demonstration projects and things occurring. We'll have a more formal review at that point, and then I think we will likely have the standards committee provider recommendation based on the standards that are in those particular specifications and in the specifications as well using the criteria that the committee comes up with, making sure that we don't have conflicts and discontinuities between our interoperability strategy. And then provide recommendations back to the office with regard to that. This gives you kind of, I hope, a larger picture of the ecosystem so that when you folks come up with recommendations with regard to policy, it sets in motion a whole series of other steps, and there will be the need for us to have periodic feedback so that we can tell you how we're doing and whether we're doing a good job or whether we're running into challenges, and sort of have that collaboration, I think, which will be a critical piece.

Part of the reason that this is also important, and the reason to give you this picture of the larger ecosystem is that we will have user communities out there that will use our specifications that come out of this framework, and they will actually ban together to exchange information. One of those user

communities, one of the groups that are using NHIN specifications and the software that's been developed against that is the NHIN Exchange or the folks that are current NHIN participants that are exchanging information. And so as we think about governance, and as we think more broadly about how all these pieces need to fit together, it's important that we sort of understand all of the pieces that are there. With that, I think I'm going to turn it over to Mary Jo, unless there are some specific questions about this particular framework, and she can talk a little bit more about governance. So I don't know if we maybe have some questions first and then we can turn it over to Mary Jo with governance.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Any questions of Doug?

Arien Malec – RelayHealth – VP, Product Management
Doug, this is Arien, if you can hear me.

Doug Fridsma – Arizona State – Assoc. Prof. Dept. Biomedical Informatics
Arien.

Arien Malec – RelayHealth – VP, Product Management
Yes. I apologize. We solved our technical issues, and I apologize for coming on late. Doug did a great job. The only other thing that I'd like to say is that I really appreciate the work and the collaboration that the policy committee and the tiger team have done with the project, and I think that the set of recommendations that Paul and Deven have come out with will help advance the state of what it is that we're doing. That's the only thing I wanted to add to Doug's summary, but other than that, I thought it was an excellent summary.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Thank you, Arien. David Bates?

David Bates - Brigham and Women's Hospital - Chief, Div. Internal Medicine
Great summary, Doug. I agree that the reference implementations are really important, and you may not have worked this out yet, but I wondered if you could say a little bit more about how you imagine that that might be structured.

Doug Fridsma – Arizona State – Assoc. Prof. Dept. Biomedical Informatics
I think there are some short-term objectives, and I think there are some longer-term objectives as well. I think, in the short term, we have a large amount of work that's been done already in determining specifications for interchange based on the NHIN gateway and adapter specifications. Those specifications, that recipe has been baked into a cake called FHA Connect. And so one of our first tasks is to make sure that the NHIN Connect application, that software, fully conforms to the specifications that are out there. And when we have kind of loosely coupled systems, and we have specifications that may give us optionality, sometimes we can have interpretation creep into how software is developed, and that can get us into trouble with that.

And so one of the things that we need to do is to make sure that we go back and make sure that the Connect project and the software that's out there for those specifications match. I think, as new specifications come in, particularly around things like NHIN Direct and the like, again, we will have folks that have built those systems, and we will then want to make sure that we've got a reference implementation that fully matches the specifications. It may be that you need other pieces and other functions around that, to be able to make it function properly.

For example, you may embed some of the specifications within an electronic health record system. We need to be able to at least pull that out and be able to describe that as a reference so that people have the ability to look at the application, see how it functions, be able to see how it interacts with other applications. We have some, through the ARRA funds that have come into the office, we'll be able to devote some resources to making sure existing software that's out there that implements our specifications can conform to what we would call a reference implementation. And that if there isn't an implementation out there then that we can sort of construct those or build those.

In large part, our goal isn't to produce new software that will go off in production and will be sold or the like. It's really a check. It's a check to make sure our specifications are correct and that we haven't missed anything. So the focus of the reference implementation really is on making sure we have the specifications right, as opposed to producing production level code that can go out there and disseminated. We see that as a potential value-add that people can bring to the table, but that isn't necessarily the goal of the office is to produce that.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Paul?

Paul Egerman – eScription – CEO
Thank you. Thank you very much, Doug. It's an excellent presentation. Thank you, Arien, for your comments. But the process you're going through, this entire testing and reference process is a great process, and you made the comment, Doug, that certification is the final step in the process. I would just make the observation for the industry, actually certification is the starting point. Fundamentally, when you get to a point where the specs are finalized, the certification process is finalized, that's the starting point, and there's a whole series of things that happen after that.

It takes vendors a long time. It takes them a year to program to and test their systems to the specs, and then they've got to get certified, and then they've got to point these to their customers. So there's a whole multi-year cycle after that. To me, it's very important that your work be somehow coordinated with the dates for the phase two certification process. My question for you is how are you coordinating all of these reference testings so that we can get it all done in time to have the certification criteria there completed, say, in the first quarter of 2011 and completed?

Doug Fridsma – Arizona State – Assoc. Prof. Dept. Biomedical Informatics
I think one of the things, and I welcome those comments. Clearly there are some getting consensus and establishing the implementation specifications and testing them. It takes some time. One of our goals in this process is that we should not wait to engage NIST in the certification, the folks that will be helping us with sort of implementing the testing strategies for certification until the end. In fact, our goal in this process is to engage at the time that we're even constructing our implementation specifications, the folks that are going to help us with the certification process.

Having NIST participate in making sure that our implementation specifications are clear and, quite frankly, if we have those specifications concretely and explicitly described so that the recipes are pretty clear, that means that NIST also has the ability to implement their testing strategies that are also going to be much more concrete and clear. If we leave, if we don't, if we leave optionality or if we don't fully specify something, then it means that we have to test to a different sort of objective, and there may be some things that we can't test against at all. I will say this that we have had a very productive interaction with NIST.

Having them involved early in the process and having them kind of review with us how we've taken policy objectives, translated them into standards, and developed sort of more explicit sets of standards and implementation specifications has been very valuable on both sides, both to make the certification criteria much crisper, and also to sort of feedback and help us understand what's possible, what's easy, what's hard. And I think we hope that this process will move this up the food chain. It may, it's still going to take us some time to do all of these other things, but we hope it will provide better quality at the end of the result because we've developed our standards and implementation criteria with the explicit directive to make sure that our reference implementations can be built and that the certification criteria can be tested.

Paul Egerman – eScription – CEO
Do you have a date or a goal as to when this will all be completed for NHIN Direct?

Doug Fridsma – Arizona State – Assoc. Prof. Dept. Biomedical Informatics
On the slide here, the hope is that NHIN Direct will be able to have the HIT Standards Committee review the first part of January 2011. I don't know, Arien, if you wanted to say anything more about the timelines with regard to NHIN Direct and those specifications.

Arien Malec – RelayHealth – VP, Product Management
Yes, and I know that the policy committee at times has felt that we'd been going rather aggressively, but, Paul, that's exactly the reason that we're under the timeframes that we are. We're trying to create the reference implementation and at least internal to the NHIN Direct project, the certification criteria so that we can provide good lead-time for the vendors who serve the providers and hospitals in the country the opportunity to build out the implementation, so I completely agree with your comments.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Paul?

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Thanks, Doug, for a very clear and articulate elucidation of the process, the framework, some of the objectives of the NHIN framework. My question surrounds the roles of the various groups, the various entities, whether it's HIT policy, the HIT standards, and ONC itself. One of the statements I think you may have looked at, you saw use cases coming out of the HIT Policy Committee. I don't know that that's what you intended because I didn't think we were into the use cases.

I thought we were more into policies and outcomes oriented sort of objectives. That's what we're trying to head towards with the meaningful use objectives for example. In your kitchen, are we the chef, or are we the consumer who wants to consume the chocolate cake that we asked for, because I think that makes a big difference in terms of how we see our roles. And so I think a lot of what you described are ONC activities, but maybe you can correct me.

Doug Fridsma – Arizona State – Assoc. Prof. Dept. Biomedical Informatics
Sure, and I probably shouldn't use food and kitchen analogies given that we're accelerated that and shortened lunch today, but I think you're right, and I probably have misspoke a little bit. I think what I'm trying to emphasize is that this framework is meant to solve problems. It's meant to solve the kinds of policy objectives and the directives that we get from this committee.

I don't expect fully flushed out use cases to come out of this committee. And in fact, if the committee says we will have quality metrics that we want to measure, and we have certain behaviors that we want to see out there with providers that satisfy meaningful use. We will need to take that and flush that out a little bit more so that we can say, given what that objective is, what are the behaviors that we'd like to see

with the providers. What kinds of functions then from those behaviors need to be supported by the technology, and what's the kind of data that needs to be exchanged to support those functions?

That will be work that we will have to do within this framework. Many of the things that have happened in the past, you know, the idea of community engagement and making sure that we get other folks that can participate, similar to what has happened with HITSP and other things, there's a place in here for those kinds of activities. But I wanted to make it clear that we're not coming up with these use cases on our own.

We're not doing them in sort of an abstract, high, in an abstract sort of grand vision way. What we're doing is we're taking the objectives that we get from the policy committee or the objective that we may get from other organizations like … projects or others that want to be able to participate in this ecosystem. And we want to solve those problems. And so, we need to be able to take those directives and go through that process.

It's not so much that you guys are going to be doing all that work. That's stuff that we will be doing within the ONC. But the directives will come from the policy.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Yes, Gayle?

Gayle Harrell – Florida – Former State Legislator
Thank you. Just one very quick observation, and I want to thank Paul for your question, Paul Egerman, because I think he brought out something that's very critical, and I'm very concerned about timeframes here and going through the – when you look at the timeline you've put up there, it's daunting when I look at what you have to accomplish and what we have to accomplish on the tiger team in order to make all this happen. I have a very difficult time thinking how we're going to do this and get products out to people, providers who are going to use and eat that cake.

I just, I'm very concerned at the quality of the cake that's going to come out of that oven when the provider has to use it. When you look at the timeframes, if people are going to start purchasing systems in 2010 actually, hospitals can actually start meeting meaningful use in October 2010, that's, you know, you're not even starting to get things out there by the time people are going to be purchasing systems. How is this all going to integrate in, and what's the impact and affect on someone who wants to come out, be an early adopter, get out there and start using a product?

Doug Fridsma – Arizona State – Assoc. Prof. Dept. Biomedical Informatics
I agree with you. We don't want anything half-baked. But I think one of the things that is important to recognize is that in many ways the things that we have for 2011 right now will need to be backfilled into this process. And I think we have the directives around meaningful use that have come from this committee, and we've identified the standards that are required to support that. And so there is not a dependency in people meeting 2011 meaningful use around this process. It's certainly not. That's not the intention, but as we look ahead towards 2013 and 2015 and, quite frankly, beyond that as well, at some point we need to start making sure that we have that kind of integration that needs to occur. It's going to take us some time to get to that point, but we have to start now to plan for that.

This is not intended to get in the way of being able to get us to 2011, but we really want to start building that framework so that, at the end of the day when we start having the need to reuse data collected for clinical summary to do quality reporting or clinical decision support that there is consistency across all the standards that we have and that those pieces will work together, and the only way that we can do that is

to start now thinking ahead towards how that might occur. This work and, quite frankly, we've got a fairly accelerated timeline, and we're making good progress towards this in the NHIN Direct project. Our goal too is that once we have this initial set of standards and specifications that we can shorten the timeframe that it takes us to get to the next one because we can reuse the things that are already there, and we're not constantly starting with a blank sheet of paper, so this is really a long-term objective that we need to start now, not one that we believe will get in the way of 2011.

Gayle Harrell – Florida – Former State Legislator
I would absolutely agree with starting now. The great concern I have is for providers out there who are going to be purchasing systems and the backfill, as you call it, that's going to be necessary and the increased expense that's going to come with that. Whatever they purchase now is certainly not going to meet the needs for what you are envisioning. The standards aren't there yet. The certification isn't there for that yet, and not anticipated for the next two, three years out by the time this all eventually happens. So there's a great deal of concern out there among the provider community. Do I purchase now? Do I wait? Where do I go? And I get inundated with questions of that sort.

David Blumenthal – Department of HHS – National Coordinator for Health IT
One more question. I guess, Arthur, you had a question.

Art Davidson - Public Health Informatics at Denver Public Health – Director
Thank you, Doug, for the presentation. I would like to ask, since we're bringing up the idea of the use cases, how is the output of the work that you're anticipating with regard to use cases going to be different or leveraged, the effect that ONC had to work on use cases in the prior administration? How is this different or what should we expect from this process that might use what had gone on before?

Doug Fridsma – Arizona State – Assoc. Prof. Dept. Biomedical Informatics
I think there's been a lot of good work that's gone on in HITSP and some of the other organizations that are out there. Certainly those standards that have been adopted by the secretary in the interim final rule, those need to be backfilled into this, as we go forward. We anticipate leveraging as much of that work as we possibly can. A lot of the early work of this framework is going to be to reuse those things that we anticipate would be useful going forward in 2013 and 2015. There is going to be some activity to kind of get that in place.

I'll also add that there's a lot of work that's gone on in other agencies, so the federal health architecture, the VA, the DoD all have done work that has been similar in terms of identifying what their core concepts are, what the data is that they need. There are other public/private partnerships like HITSP that have been working on some of these activities as well, and part of the goal is to begin integrating those into a common way of representing our concepts and our services so that there is the ability to leverage work that's being done in lots of other places and bring that to the table.

I think the other comment, and then I'll stop and turn it over to the other folks here at the table, and that is that HITSP produced some very nice implementation specifications, but much of them were kind of Word documents that had links to other standards, organizations, or that had different specifications, and it was a challenge to be able to maintain and make sure that they were integrated. HITSP did a good job trying to do all of those things, but if we want to accelerate the process, and to Gayle's point, to make sure that we can be very responsive, we need to shorten the timeframe. And the way that we can shorten the timeframe is to be able to provide tools and infrastructure that will allow us to do this faster. And so, we're trying to get to that point with all of this and leverage as much as we can, both of the work that's been done in the past, as well as kind of going forward with other agencies as well.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Let me move us along. I think Gayle and Paul have raised both a very important question that has to do with timing, synchronization of the capability for exchange and the timeframes around meaningful use. They're important questions. One of the reasons I think this committee was relatively modest in its recommendations around exchange for 2011 and 2012 had to do with its recognition that the work that Doug is doing and that is going on with NHIN Exchange, the work that the states have been doing are still incubating.

Therefore, we had to compromise on our aspirations for the first stage of meaningful use. In fact, the first stage of meaningful use only requires in the NPRM the demonstration of a capability. And that that's going to, itself, be something of a lift, but it's a lot less than actually doing exchange in a robust way, and we're going to have to try our very best to make sure that within the timeframe people have to have to reach meaningful use, which is in the NPRM, the last quarter of 2011 or 2012, that solutions are available if that turns out to be where we end up in the final rule, that solutions are available in a way and in a time that can be, that certification of those capabilities is possible, and they can be included in the available records.

I think throughout this journey that we're on, we're going to have to be continuously upgrading the capabilities of the systems that people buy because 2013 is going to be different from 2011, and 2015 is going to be different from 2013. That's going to be a challenge, but one of the things that I think we're, in some sense counting on, is the ability of vendors to continue to mature their products after they're installed. And some vendors are going to be more able to do that than others, and that's going to be one of the things that I hope will be part of the discussion, as people acquire systems is an evaluation of the capability of the vendor to do that.

But that, I think, is built into the framework we're doing that is change over time, innovation over time. If we were to say that everything has to be ready, the cake has to be fully baked in 2011, we would be paralyzed really in terms of our hope for what we can accomplish with health information technology. Having said all that, we do have to go back and look carefully at this timeframe against the timeframe for 2011 and 2013 meaningful use and, I think, come back to you with at least an explanation of how we see it all fitting together.

All right. Let's move on to Mary Jo, and another obligation of NHIN governance.

Mary Jo Deering – ONC – Senior Policy Advisor
Thank you very much, David. I think that when I listen to Doug, he makes technology sound tasty. I'm happy to see some friends here who knew me back when I was the lead staff for ten years of the NCVHS workgroup on what was then called the National Health Information Infrastructure, the first and only lead staff, as it turns out, as that work has transitioned and taken on a new dimension. But I'm really happy to have been at ONC these past few years for what's really a final push to get us past the tipping point to the effective use of EHRs, not only by providers, but by consumers and patients.

And so today we are asking for your help in what is really a critical piece of that effort, which is establishing governance for the Nationwide Health Information Infrastructure, which as you know, and have to quote this definition, is the set of standards, services, and policies that enable the secure exchange of health information over the Internet. And because this is a very complex issue, which is essential to establishing trust in information exchange, we want multiple points of input. This is the beginning of a conversation, certainly not the endpoint. And so today we're asking for your help in framing the first of those steps, an initial request for information, which we want to get out in early August. That will be followed by an NPRM early in 2011, and with the final rule out next summer.

Some of you remember that ONC has been actually looking at the issue of governance since back in 2004 when we did a first RFI on the NHIN and governance was … back then. So the slides that I'm presenting today build on a lot of work over the years and, more importantly, on the work of this committee and its workgroups today, and specifically the work of the NHIN workgroup and the good work of the privacy and security tiger team, which we will be working with in the future. What we're going to do today is pose some potential questions for the RFI, and we need your input.

We know that these questions aren't the only ones. They may not be the best ones. We're not asking you to answer the questions today. We're not asking you to edit the questions today, but we do want to know is this what we should be asking. What should we be asking at what level? Because this is a new and complex area, and many people haven't had this introduction, I'll go through my full presentation before going back to some of these issues. Again, when you see questions up there, it's not that we're looking for your answers.

There's a single line in the HITECH Act that says the National Coordinator is to establish a governance mechanism for the Nationwide Health Information Network and this has to be accomplished by rulemaking. Why do we need rulemaking, and why now? We have to be sure that users have trust in how information is shared, that the exchange really works, that consumers' and patients' expectations are met, and that the NHIN is optimally used to improve health and care.

But we have some very specific pressing needs too. Without final governance, the NHIN Exchange can't expand and grow beyond a specific category of participant that are currently limited by legal guidance. We need ways to certify or credit new entities like health information service providers. Rulemaking will recognize that there is a baseline of governance already, including the rule of our advisory committees, and we're going to look for complementary mechanisms to fill the gaps.

Setting the scope of rulemaking is a critical first step. Who and what is governed? When and how? Who makes the decisions, and what oversight and accountability are needed? We thought it would be useful to use the HIE trust framework, which was put forward to you by the NHIN workgroup to set the context for today's discussion. As you recall from your prior discussions, these five areas are not really principles. They're categories of attributes that are needed for trust.

I will just read the headers of them in the interest of time. The areas are agreed upon business policy and legal requirements, transparent oversight, enforcement and accountability, identity assurance, and technical requirements. It's premature to know whether these five will actually frame the rule itself, but we'll use them today to tee up the big questions that have already percolated upward from a lot of work, including yours.

First, there are some overarching questions of scope. The biggest is, of course, whether participation or compliance with NHIN standards, services, and policies should be optional, you know, preferred, mandatory. Do we want to brand the NHIN? Are some governance mechanisms required as common to all kinds of information exchange? Should any use of NHIN standards and services be outside governance? When should we use the levers that we do have, rules and regulations, certification and accreditation, incentives for compliance, recognition of best practices, watching the marketplace develop, any combination of the above?

Starting now with the first of our buckets, which is the business policy and legal requirements for expectations. The consumers, patients, and providers, and other stakeholders to be confident that information is being used, protected, and disclosed appropriately. Many specific issues need to be

addressed. When should consent be required and for what: to populate an RLS, to disclose or reuse PHI?

What about more granular data? How about data segmentation, particularly data elements? What requirements are necessary to assure data integrity and quality? Should requirements for consent and data use vary by exchange model? We currently have the exchange, which is the query and lookup model.

We're working on the directed secure routing. There well may be other exchange models in the future. How should we specify appropriate purposes for using, exchanging, and reusing data, and how should we minimize data required for various transactions?

Transparent oversight: Oversight is intended to be management, maintenance, supervision, and monitoring of the trust relationship and exchange activities. There should be as much transparency as possible in the oversight mechanisms that are employed to protect the information and the oversight process and results, including the findings and consequences. The nature of the oversight and the mechanisms used will depend upon the exchange model, the parties involved, and the needs that the exchange partners themselves identify.

Some of the key questions: Is there a rule for federal and/or state oversight to monitor and address abusive market behaviors. Is there a need for federal mechanism of oversight over information exchange organizations? What about the appropriate federal and state roles? How can transparency and open processes be assured for setting Nationwide Health Information Network policies and technical requirements? How can transparency in oversight and accountability be assured for NHIN?

Enforcement and accountability: Every exchange partner has to be accountable for its exchange activities and must be prepared to answer at multiple levels. For example, to individual subjects of the exchange information, to other participants in the exchange, to third parties who are providing enabling functions, certifiers, accrediting bodies, governmental entities. Methods for confirming, detecting, and enforcing compliance and the consequences may vary at each level. You could have the loss of a patient who doesn't trust the provider, loss of business, enforcement of penalties and, if appropriate, redress.

Here are some key questions. Should there be a certification or accreditation program for intermediaries like HISPs or participants, as in the exchange? If so, what are the roles for the certifying of accrediting body? What are the requirements for certification and accreditation? What are the limits? What other types of enforcement and accountability measures should we consider: regulatory requirements, contractual requirements?

Identity assurance: Exchange partners will not exchange information with just anyone. Each has to be confident that they're exchanging information with whom they intend to exchange information. Each exchange partner, therefore, validates and should maintain an audit log of the identity of those with whom it exchanges information and validation of parties to the exchange can occur in a number of ways, either based on manual determinations at the practice level using identity proofing and digital credentials to validate members of the network, etc.

Some of the key questions: Should there be identity assurance requirements for providers accessing clinical information systems or specific data where patients and consumers own access, for participation in the NHIN and in those transactions? Should there be mechanisms to validate the processes themselves and what mechanisms?

Technical requirements: In all exchanges, the partners have to adhere to technical standards to insure interoperability, privacy, and security. I'm not going to say much about this because … half-hour that gives you a good introduction to all the processes that are going to be required here. But again, you can see some of the initial questions that we've teed up for you. And based on what you've heard Doug say, is there additional testing and oversight that we need? Some of the mechanisms that are available are the thresholds that have been established by federal agencies for exchanging information. What level of interoperability in the NHIN is required to meet the policy goals that you were setting for us?

That's the end of my presentation, and I look forward to your comments, questions, and suggestions. I should introduce my colleague sitting next to me is Steve Posnack, who is actually currently the acting director of the Office of Policy & Planning … Jodi Daniels maternity leave, and you probably know him as Mr. Regulations, so he's going to play a big role here.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Thank you, Mary Jo. At a very intuitive level or simplistic level, I think that this discussion begins with a task that was assigned us by the Congress, and in a very narrow way, the task is embodied in this one sentence that says that the Office of the National Coordinator shall—I forget the words—establish or maintain a governance mechanism for the NHIN. But that's not really why we're here having this discussion. We're really here having this discussion because of the broader mandate and desire to create an interoperable, nationwide, private and secure, health information system.

The hypothesis is perhaps more than a hypothesis. The sense is that this won't happen by itself. That there will be a continuing need for a referee, an organizing force, and that's sort of a way of describing NHIN governance. It's governance of the interoperability system that we create, and some of the questions that Mary Jo put up are questions that you have to begin to consider once you go down the path of thinking about what that referee – I hesitate, given our experience with referees in South Africa to talk about referees right now – or umpires, given the experience with umpires, but given that organizing force, what is the role of government? What is the role of the private sector? How do they work together, and what are the specific tasks that need to be taken on and the problems that need to be solved over time?

The issue is made more urgent by the fact that we have a group of organizations, some public, some private, that are now trying to use the NHIN to exchange data, and they are trying to decide how to move forward on a whole series of technical and legal issues. The general council has ruled that they can't do much unless we help them do it. They are mostly independent contractors with us. Some are grantees. They need to be able to figure out how to bring in new groups that want to work with them, and they have no framework for doing that right now. They have no legal authority, no mechanism.

For the states who have received our health information exchange funds to become members of that exchange, let's say they decide, a state has decided that they want to use the NHIN Exchange, as we've been developing it within their jurisdiction as the place where vendors can hook up to, to carry on exchange. We need to give them a docking system to this process, and that requires some – a process for docking, conditions for docking. And once you go down that road, a series of legal and policy questions come up. So it sounds, the phrase … governance sounds very abstract and almost like a political science exercise, but it's actually got very real issues in the short-term, and those are the issues that we have to deal with. Then the many, you know, pants on fire, short-term issues we have to deal with, this is one of them.

Comments, Gayle?

Gayle Harrell – Florida – Former State Legislator
Thank you very much. I appreciate your overview and the questions that you have raised are so significant. I think the more rapidly we move forward with this discussion and perhaps we need to put a whole segment into a major discussion on this. We have got to have a framework for governance established immediately. The states are moving forward, and without some guidance, I believe, to be able to all pull together into the NHIN and be able to connect up across states, we have got to have some overarching governance established.

Most importantly, the reason we need to move forward as rapidly as possible in this segment and get things out there in order to have the public confidence to do it. You're not going to get public confidence and acceptance of this, especially on the privacy and security realm. People have to got to know that their records are going to be secure and be changed appropriately with people they trust, and that trust mechanism is critical. So I can't say how important governance is, and I would like us to move as rapidly as possible and judiciously, making sure we cover all the bases with this. And I would propose that we need to perhaps designate a significant amount of time in one of our meetings to really question this.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Charles?

Mary Jo Deering – ONC – Senior Policy Advisor
David, could I just make one? I forgot a process step that I think speaks to that very well. We had a conversation with the cochairs and others, and our proposal is that we would ask both of the committees to hold full, perhaps two-day hearings jointly in September, as early in September as possible, just a heads up, possibly the first week right after Labor Day, just to emphasize the comprehensiveness of this approach. The panels could be put together by individuals with expertise of some of the sub-workgroups to contribute to a whole picture of what has to go into this. So we'd very much welcome a very robust, very focused, very quick timetable, and we'll be working with the tiger team in August very specifically on the privacy and security aspects of it.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Charles?

Charles Kennedy – WellPoint – VP for Health IT
Mary Jo, thank you for that presentation. My question is, we've talked a lot in the meaningful use subgroup about the importance of a learning health system, but I feel like clinical research tends to get a little bit of a short … in a lot of work, and I saw the notion of data reuse mentioned under business policy and legal requirements, but I wonder if that's sufficient for where we need to go to make a learning health system real, in other words, clinical research, maybe leveraging the NHIN for a clinical trial even. I would think we're going to need a fair amount of governance around those types of issues and wonder where that might fit.

Mary Jo Deering – ONC – Senior Policy Advisor
The short answer is that that will come out through the rulemaking process, but a slightly longer answer is first you may not know, I came from NCI and the cancer biomedical informatics grid whose interest in the NHIN is exactly that. But also, I think you may have heard from Chuck Friedman here, and you may be aware of our office is interested very much so in moving in those directions, and so there's every intension of making sure that is included in there, but again, the specifics will have to come out through the process.

David Blumenthal – Department of HHS – National Coordinator for Health IT

Marc?

Marc Probst – Intermountain Healthcare – CIO

Thank you. That was terrific, Doug and Mary Jo. Both of you, that was great. It seems to me that, well, one, what Gayle was talking about, the relative speed of what we need, I mean, what we're dealing with even locally and some of our issues, we really need to get this governance in place.

As I go back to Doug's presentation, I was really intrigued by the chart, the framework that was the thousand flowers and the command and control. In this, when you talk about speed, and obviously command and control allows for a lot faster decision-making, and where in the governance process is the decision of what should just be dictated. Probably a bad word, but that can be because a big problem with standards, and I'm sure you run into it with NHIN and a thousand flowers is every one of these standards is out there. It's changing at a pretty rapid pace, and so coming up with that recipe for the cake that even looks like a cake is pretty difficult. Where in governance do you make those priority decisions or those – you know, who decides what should be done with command and control versus a consensus process?

David Blumenthal – Department of HHS – National Coordinator for Health IT

It's a great question. It's one that we grapple with daily at ONC, and we look at what our authorities are, and we look at what our real authorities are compared to our legal authorities because enforcement of a command is a nontrivial issue, and we have a very big country with lots of autonomous regions, and so when you need people to work together collaboratively, ordering them to do so is not always effective. And so I think that the question of where command works and where consensus works is one that evolves over time and is constantly and evolves in terms of people's willingness and also in terms of understanding.

This policy committee is one that we're going to be looking to, to give us advice on that because you were picked by the GIO to be on this committee because you represent points of view, not necessarily institutions, but you have backgrounds that give you insights into the way particular stakeholders might react. So we desperately need your advice on precisely that issue, keeping in mind that we might like to command things at time. It may not work to command things. We could develop standards that prescribed every single piece of an electronic health record, and no one might adopt them because they didn't work, so it's something that we're constantly asking ourselves.

We've been moving forward. We're going to have a meaningful use regulation. That's a pretty big command. That's not really a command because it's a voluntary program. We have standards and interoperability, standards and certification regulation. That's kind of a command and control, but not really because its only influence is if you want to get certified to enable someone to get meaningful use. All these are judgments, but if we had an obvious answer, we wouldn't need this committee to help us.

Steve?

Stephen Ondra – NeHC – Senior Policy Advisor

Yes. Echoing some of the other thoughts, as an earlier implementer of some of this, the VA, this is not a theoretical problem. This is a very real issue that we're facing, and I really want to applaud what ONC is doing, both in terms of the health information exchange efforts, and also the NHIN governance. We see an immediate need for this, and look forward to working with everyone on this committee to help ONC push this forward.

Mary Jo Deering – ONC – Senior Policy Advisor

I'd like to thank VA for offering Linda Fischetti up over the years, who has been a big contributor to earlier considerations of governance issues, so thank you.

David Blumenthal – Department of HHS – National Coordinator for Health IT
And hopefully we'll continue to offer Linda.

Stephen Ondra – NeHC – Senior Policy Advisor
We will.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Latanya?

Latanya Sweeney – Laboratory for International Data Privacy – Director
Yes. I wanted to say, sort of with … respect to Dr. Blumenthal and to the work of Doug and Mary Jo, and just sort of echoing a little bit from the comments made by Gayle and Marc. I too was very taken by that graph of the thousand flowers blooming as opposed to command and control. But I would pose another model that has worked very effectively in other areas, and it's where you produce a climate where you allow a lot of freedom, but in fact you provide the right kind of technology and policy incentives that create a convergence. I think one of the best examples of that is the World Wide Web.

When the World Wide Web was introduced in 1995, the Commerce Department drew us some more kind of diagram, almost exactly that diagram, and said we don't have that authority. We can't make people respect privacy on the Web. We can't provide. We can't force a standard by which credit cards can be reliably put in place. And so what happened was a group of academics and institutions got together and formed the World Wide Web consortium. That consortium was able to do some deep thinking and not have to rely.

The problem, you know, we do a lot of great work and obviously has done a tremendous job, done a lot of great work on the consensus and these kinds of efforts. But really in the technology space especially where innovation is so, can totally change the conversation, we need a kind of deep study with the people who can have the opportunity to do that. I've seen studies done over a long period of time is having the right people with the right focus for a short amount of time. The World Wide Web moved fairly quickly.

I remember the window of opportunity, the window of complete with … January. I remember in January, there was a huge conference. Everybody was screaming about, oh, my God. How can we get people to use the Web? Before that summer, they had the technology in place, and by the next Christmas, there were record sales of online activity using the Internet, using credit cards over the Net. It's not a particularly long period of time to come up with these kinds of innovations and opportunities, but you have to kind of create the right environment, and I would encourage you to kind of rethink because even the diagram doesn't give you the space … to allow that kind of framework.

Judy Sparrow – Office of the National Coordinator – Executive Director
Neil Calman….

David Blumenthal – Department of HHS – National Coordinator for Health IT
Neil?

Neil Calman - Institute for Family Health - President & Cofounder
Hello. Hello, everybody. Sorry I couldn't be there with you today. Just to comment on one of the things you said, David, and you had mentioned after the prior speak that you were concerned, not concerned,

but you were hopeful that the vendors might be, would be able to come along as the process of these standards evolved. And it brings to mind sort of the other side of this whole equation, which is the feasibility of what's going to happen as people continue to purchase systems and other things, and what kind of responsibility we have to kind of make sure that this implementation effort that's going on across the country with RECs and everything else, that people aren't spending a lot of money on systems with vendors that might not be able to come along. And yet, you know, how we would go about doing something at a policy level about that is, I think, something that we need to consider.

One of the most concerning things, I think, is that the way we're sort of talking about this is that this is an ever sort of evolving process that new standards are going to be coming out all the time. New things are going to be happening on sort of an evolutionary basis. And I wonder if there's not, you know, similar to kind of what happened with meaningful use. If it's not important to define some quantum dates and say, you know, these are the 2011 standards, and we're now working on standards for 2013 or 2014 or 2015, so the people at least have some sense of stability at points during this process that what they're getting now, if it meets certain standards, will be able to serve them for a period of time, and that it's not a constantly evolving process where people could find themselves. Yes, they were fine. And I don't just mean the certification of their EHR. I mean their ability to do all of the things we're hoping they're going to be able to do with their EHRs.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Well, great comment, Neil, and I think we're hoping that the meaningful use rule and standards and certification implementation specifications and certification rule will provide that groundwork for the first period of time, and we can then message. As a result of that rule, we can begin to message what the next stage will be, and so this is a kind of awkward few weeks because everyone is holding their breath waiting for a rule, and there's still a lot of uncertainty. There'll be more certainty very soon, and then we'll have another problem, which is people won't like the certainty. That's another thing all together. Adam?

Adam Clark – Lance Armstrong Foundation – Director for Health Policy
Thank you, Mary Jo. I just want to give a comment at least on the area of enforcement and accountability, a little bit from the patient and that maybe these two areas could be separated or broken out because at least what I'm looking at tends to weigh much more on the enforcement mechanism or enforcement area, which to me comes off very much as government mechanisms for this. And I don't think necessarily that the patient community is going to be as concerned about it. What they will be concerned is the accountability. If you are going to be trying to build a trust mechanism, they will want to know what are the repercussions. We don't care who is doing them, but what are they going to be. And I think that there's going to be a lot of input from this community on if we're going to trust the government, the states, and our doctors and everyone with exchanging this. How are you going to assure us? Any ways that we could start to break this down and help educate the communities on the value of this because I do think there is tremendous value, and we need to reassure them that this is going to be at the highest level of trust.

Mary Jo Deering – ONC – Senior Policy Advisor
Thank you. We welcome that comment.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Paul?

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
This question of command and control versus a thousand flowers is certainly a novel one, but I wonder if sometimes the answer isn't actually easier than we think it is. So a thousand flowers may sound good,

but sometimes you end up with a lot of weeds, even in the eyes of the gardener. I'm reminded that there was—

David Blumenthal – Department of HHS – National Coordinator for Health IT
I just want to note a change in metaphor here.

W
…to gardening.

M
…growing….

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
My wife is an ICU nurse, and every month you have to go see who has got the evening shift, who has got the night shift, assuming that you have to dictate it. It turns out one time they did an experiment and said everybody just volunteer for what you want, and it worked out. In other words, the answer was easier than worrying about the question.

Another way of saying it, sometimes there's a silent majority that doesn't speak, but they've actually all come quietly to the same conclusions from their experience, and that's leading me to something that David Lansky – so we serve on the California e-Health Advisory Board, and the mini country of California isn't necessarily known for its conformity, but when we're struggling with the whole privacy and security or other things that are barriers or challenges to interoperability, sometimes you almost say, gosh, I wish the feds would just do it because it often is actually easier.

And let's take it. Privacy is a good example where we all may have different thoughts … may have their own rules, etc. But once you come to the conclusion that by having 50 different rules, you've actually disarmed every one of them. You've undermined every one of them, and that it's actually easier, saver, more reliable, and gets you to better patient outcome if we had uniform standards, whether that be privacy or technology or even identifiers.

So I wonder sometimes the answer might be lurking underneath if only we dared to speak it like maybe you should all volunteer for what shift you want, or maybe we should just have some privacy or some certain sets of standards that gets that for us and makes all of our jobs easier because all of a sudden, in the past … the markets, everybody is on their own time schedule. One of the things that HITECH brought to us was a uniform or synched up time schedule. Now that is a mandate. Yes, it's a voluntary program, but it's not voluntary in the real world.

And I wonder, now that we're all synched with the need to exchange data, which means we have a need to have some way of protecting patient information and a need for all the systems to understand it, maybe now is the time to address some of the things we haven't been able to do using the market, in the market that now we all have a common need, which actually turns out to be time. And we might actually be, because when I sort of talked about this at our California setting, a lot of head nodding that it's that whole silent, you know what? It would actually be a lot easier, a lot safer, and a lot more efficient. Maybe we need to even start that discussion of whether things that we could now get some agreement on because we all need it at the same time, and it's just a lot better if we all do the same thing.

David Blumenthal – Department of HHS – National Coordinator for Health IT
It sounds like a very wise comment. I'm looking at the revised schedule, and I see that we're up against a time limit. Judy, why don't we take yours as the last question in this segment of the discussion?

Judy Faulkner – Epic Systems – Founder
Just a couple comments: I look at a thousand flowers blooming not as a thousand of the same flower. In other words, it's not consensus, but the ability to have a thousand different flowers blooming in a very nice garden, and maybe some weeds. A weed is just a flower in the wrong place anyway.

And I like command and control when it's an urgent decision that has to be made rapidly. And I really agree that for the best outcome in the end, as much as we can have innovation there and still know when we have the – I think, Paul, you're going to make a higher level decision, as I heard you right, and if I heard you right, I want to support that because I think sometimes when I listen to our conversations in some of the subcommittees that I'm on, they're so detailed, and we are missing the forest because we're walking all around in those trees. And so I think if the command and control could be at the higher level, and at the lower level we have different flowers blooming, I think that would work well.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
…cake.

David Blumenthal – Department of HHS – National Coordinator for Health IT
All right. I'm going to move us along. I want to thank our panelists for … presentations. They've just given us more work to do. That's sort of the truth, the fact we live in. We do take away your, and appreciate the committee's sense of or shared sense of urgency around NHIN governance discussion. George, welcome back.

George Hripcsak - Dept. of Biomedical Informatics Columbia University – Chair
Thank you very much. Thanks for having me. Good morning, and thank you to my colleagues on the workgroup. I'm going to be talking about the hearing that we held on June 4th on eliminating disparities, a focus on solutions.

We had previous had two hearings, specialists and patient engagement, where we had people testify about disparities and tell us the problems. We hoped with this hearing to see what we could do about it. The sponsor for the hearing was Neil Calman, who is on the telephone.

We held three panels: health literacy and data collection was the first, culture and access. We took a broad view of disparities, things you'd normally think of, race and ethnicity, language, health literacy, and then also extended migrant and seasonal workers, children and the elderly, and the special issues that come up bringing meaningful use in those age groups, and the homeless, which bring on not only that they tend to have people with health disparities, but there are unique problems with the homeless also.

I'm just going to have two slides, general themes and then what we talked about as some solutions. The first main thing that hit us is that the underserved is not a group of people. The underserved is a name for several groups of people who are not served medically, so … come up with a solution for how we address meaningful use in the underserved, there's not one set of solutions, and that's the corollaries in the second item, engage the community and design.

We had someone testifying from north of the Arctic Circle, and we had someone from the inner city, and those two groups have different issues that need to be addressed where the homeless is another one where it has a separate set of issues. The important thing there was that perhaps the lesson is that we need to keep the underserved in mind and develop a culture and sensitivity to it, but there's not going to be one or two policies that solve the problem.

But I will say that if there is a comment theme … it's about communication and sharing information, so a lot of the day we talked about health information exchange, personal health records, mobile devices, new media, kiosks, and second monitor. Second monitor means when the doctor is busy with her or his back to the patient, we need a monitor for the patient so that patient can see what the doctor is doing, basically another way of basically improving communication. We need to not only perhaps not just look at disparities, but report them so that we have a central resource where we can judge how we're doing on health disparities, and I'll go into that on the second slide.

Requirements, education, and training, this is not going to be a solution where you just put something in the EHR, put something on the Web site that we need – that the people we're serving, that is the community, the patients, the customers, there will need to be efforts in education and training to get there. And because of that, we're going to need the trust of the community, and we'll probably need to exploit community organizations, and I'll cover that again on the next slide. Then time is a challenge. There was a specific example where there's a community actually … north of the Arctic Circle where they have good health information exchange between the community organizations and, I guess, the local hospital or clinics. But because of meaningful use, they're adopting a new electronic health record on the other side, and so they've lost their connectivity, so we've actually set them back in a sense was one of the things they pointed out. So it's a challenge in how we move forward so quickly without leaving the underserved behind.

So what can we do? For the meaningful use workgroup in particular, one that we want to report and track measures stratified by disparities. That is not just ask people to do it, but actually get the information back, presumably to CMS, and be able to track how we're doing as a nation.

One great presentation showed that if you just divide people up into a small number of race or ethnic groups, you miss a lot of the important information, so I think the example was Asian. If you report performance in cancer for Asian people, you miss the fact that in those subgroups, some are doing extraordinarily well, and some are doing extraordinarily poorly. And, on average, it looks like you're doing fine, but in fact there are problems that need to be addressed.

Therefore, we need to go to a finer level of granularity when we measure things like race and ethnicity. Luckily, the *Institute of Medicine* published a report in 2009 on how to measure race, ethnicity, and language. It addressed both how we can standardize, so we come up with the same measures across all our implementations, but also be able to go into this finer level of granularity.

Finally, patient materials that are appropriate to language and culture are critical, and we have to decide to what extent that goes into the meaningful use criteria. Then a number of other things that were discussed that are not really the purview of the meaningful use workgroup, but we wanted to bring up here, so one is coordinating the many training activities, for example, the regional extension centers need to probably train small provider staff on race, ethnicity, language—that's what the REL is—and on how to stratify and why we want to stratify by that. Next, we want to expand the regional extension centers. If it covers, say, a tenth of the population, how do we reach out, and especially in this group that we're talking about, these groups that we're talking about today, and so we may need to build links between the regional extension centers and the community organizations that are in fact sharing the disadvantaged populations.

There was a … example … there are programs out there that offer funds for various purposes and there was a question presented to us of whether those funds, so the telecom program can only be used for certain very network specific purposes, and could that be broadened to purchase hardware to serve meaningful use. We don't know the answer to that, but it was a question that we agreed to bring up.

And, last, many groups, we had a lot of great presentations that day that are working on addressing health disparities, and it would be good if there could be a central repository for materials and for experience. The National Library of Medicine is doing this in some ways, but just looking at how we can share our experience was the final point.

Then let me just point out our upcoming hearings, and then I'll take questions on the other slides. On July 29th, we have a hearing on population health, population and public health, and Art Davidson has agreed to be the sponsor for that. And on August 5th, we have a hearing on care coordination, and David Bates has agreed to be the sponsor on that. And so we'll be giving more details. Actually, on the public health hearing, we're pretty far along on doing that planning. We're not done finding all the slots, but we're pretty far, and I believe, on care coordination, we'll begin next week or so starting that planning. Neil, would you want to add anything about the disparities hearing?

Neil Calman - Institute for Family Health - President & Cofounder
Yes. I just want to add two points if I can. Another issue that came up was that I think we all feel responsibility to make sure that the safety net providers, whether they're outpatient providers or critical access, rural hospitals, or public hospitals are not left behind, as we implement electronic health records across the country. I think it's very important and came up at the meeting that this be monitored on an ongoing basis. The rates of implementation, we should, as a policy committee, be monitoring the rates of implementation amongst the safety net compared to the rest of the organizations because I think otherwise the people they serve will also be experiencing disparities, as we continue to roll out these systems. And I'd like to at least engage in some discussion about how that might take place.

Second of all, I've gotten a number of e-mails since the hearing saying we did forget a group that experiences substantial disparities, and those, and that would start with collecting information on sexual orientation and gender identity. And so there may be an opportunity. I'm expecting some information to be sent in writing, which I will share with the committee about how that information might be collected and used to make sure that that population doesn't experience the same kinds of disparities that we're looking to protect people from in terms of race, gender, and other kinds of disparities. We'll be, definitely we need to look at that. We did not do that. And I'd like to at least think about how we could figure out whether we can monitor rates of implementation across the country in terms of safety net providers.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Okay. Any other comments? Marc?

Marc Probst – Intermountain Healthcare – CIO
Yes. Just quickly, kind of going back to our last conversation, this seems to me that it's something that clearly we need to deal with, so thank you for having that hearing. But the quicker we could get just standards for data, what data we want to collect, and so the vendors or others that are developing systems, as long as we understand what we need to put in there, this seems to me to be a pretty solvable problem if we could just get to the what do we want to collect stage.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Yes, well, the standards regulation will help with that, and over time, perhaps the meaningful use requirements will as well. It won't help us solve the problem; help us document the problem. I just want to say that ONC has identified this as an area of priority for us and that we are thinking about ways in which we can try to assure that our activities don't enhance disparities and preferably reduce them. But history of new technologies in this field is that they tend to be adopted to or by majority groups, not by underserved, and not made available as readily to underserved minorities. That's something that's on our mind.

Neil Calman - Institute for Family Health - President & Cofounder
I think that since we're putting so much money into the REC that that is at least one first level at which we could monitor rates of implementation through each of the RECs and the safety net providers in the communities that they serve.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Paul?

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Another piece that was touched on is in addition to the technical standards, as Marc was talking about what data elements, is the people-ware, which is, how do you collect, in a sensitive way, this information? And some of the test RECs were talking about how if you just explain, first, they're very weary initially of saying why do you want to know that. In fact, it would be the fear is that it would create more disparity. But once you explain to them, and that's where the training comes in, they readily buy in and share that information. Another group that we did miss, and I think we may find a way to incorporate that in the upcoming hearing or some workgroup call is Americans with disabilities as another area where disparities can occur, so that's one that we did not hear from in this particular hearing, but we don't want to miss….

David Blumenthal – Department of HHS – National Coordinator for Health IT
Good point. Gayle?

Gayle Harrell – Florida – Former State Legislator
Thank you. I just want to commend Neil for bringing up safety net hospitals, and I think that's a critical area that we need to address. Most of our, at least in Florida, a lot of our safety net hospitals are underfunded and become – this is a real issue for them. And if they have a large residency program and they're running clinics, whether or not their physicians have separate identifier numbers becomes a real issue on getting reimbursement and early meaningful use dollars, incentive dollars. Our safety net hospitals really need to be looked at as a separate category because they are facing huge problems.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Thank you. Judy?

Judy Faulkner – Epic Systems – Founder
I think it's good to monitor how they're doing, the safety net organizations, with the use of the technologies, but one of the concerns that I've seen and maybe Neil, if you know how to handle this, I think it's something the group could do to help the vendors would be to be able to help us know who really are the safety net facilities. Certainly on the amateur side, there are a couple of qualified health centers. But then there are other facilities that serve the underserved, the free clinics and others. How are they defined? On the hospital side, you have the safety net **M**-dish. You have pickle-dish.

But there are many others that feel that they are truly serving an awful lot of the underserved by a great percentage, and they have many patients who aren't paying, and they see themselves as a safety net, although they may not be viewed as such by any group. And sometimes you have more, I think, of the underserved that they're serving than some who are actually on the list. A good ability to identify who they are would be very helpful.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Yes, Charles?

Charles Kennedy – WellPoint – VP for Health IT
George, thanks for that report. One of the things I've noticed is a lot of safety net hospitals will break even or maybe lose money on the provision of care itself and have one particular department, for instance, labs, where they actually make their money, and this enables them to stay in business. As we look at these issues, I'd encourage us to be aware that it's not just a matter of affording the technology, but once the technology is out there and the safety net hospitals, let's say, lab is not connected, they may very well lose the revenue source that keeps them operating. So we need to look at the secondary impacts of what rolling out health information exchange may have.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Thank you all for those comments. Thanks, George. We're going to move now to a report from our privacy and security tiger team. Just to draw connections, one of the reasons why this tiger team is running like a cheetah is because of the time imperatives that Gayle has identified, and Arien, and that we are trying to satisfy with the need to stand up the NHIN Direct because a lot of what Paul and Deven McGraw, who can't be here, and Joy, who is our chief privacy officer, are trying to work to get to quickly enough is a set of privacy and security recommendations that can inform the construction of the NHIN Direct. We've been told many times by people around this table that we should start with policy and not let technology dictate solutions, and that's what we're trying to do in this case. Sometimes the technology looks easy when you try and do policy though, so I'm looking forward to hearing from Paul and from Joy. Thank you for being here.

Paul Egerman – eScription – CEO
Thanks, David. Good morning. I'm Paul Egerman. Deven McGraw, my cochair, got stuck in, I think, Los Angeles or maybe San Francisco, but she is unable to be here, but I did ask Joy to sit next to me because I felt a need to have somebody who actually really understood HIPAA to correct me every time I made a mistake. Even though I am a cheetah, I do occasionally make mistakes, so I appreciate your help, Joy.

What I'm going to do is explain a little bit about the tiger team, tell you what we're doing, and actually we have two recommendations, and so I'm going to ask for your approval of two of our recommendations. Here is our broad charge. We were established by the Office of the National Coordinator to aggressively address some privacy and security issues related to health information exchange that must be resolved over this summer, so these relate to the health information exchange organizations that were recently funded related to some of the governance material that Mary Jo Deering just presented. And we took four of the members of the tiger team. We have individuals from the policy committee, from the standards committee, and also from NCVHS.

We have actually a fairly small group of people, even though we have some pretty broad representations. Here you see the list of people that are involved. There are about 12 or 13 of us. We do have supporting us, we have Joy Pritts from ONC and Judy Sparrow, of course, is very helpful, and also not listed on the screen, but Adam Greene from OCR, the Office of Civil Rights, has been extremely helpful, as we've gone through all these processes, giving us a lot of great input. These are the members.

We have been meeting already. Here is a schedule of our topics, which is, again, very aggressive. You see in the month of June, the primary topic, which I'm going to talk about a little bit more in a minute, is this concept of message handling and directed exchange, which is something you may wonder what in the world is that. I will also explain that.

In a couple of days, June 29th, we are having a hearing on this interesting issue of consumer choice that's on, I guess that's on Tuesday, and we're going to actually have consumer choice and technology at that

hearing. We have some consumer advocates coming to speak, including Deborah Peal, but we also want to make sure we provided a balance to you, and so we have Jim Walker from Geisinger, who gave a lot of presentations on patient safety. So we're going to be looking at the balance between patient safety issues and consumer choice issues, and we're also going to be looking at an interesting balance that some people say is a challenge between medical paternalism and individual sovereignty, and so we will be examining that. This is a hearing that you don't want to miss.

In July, we are then going to hit some very difficult issues. We're going to continue our directed exchange. We're going to look at various HIO models. We are going to address these consumer choice issues, which means consent and sensitive data. It means interstate exchange. Then in August, it says we're going to be doing governance. We don't expect to do all of governance, but instead, we're synchronized with what Mary Jo Deering presented with the entire governance, NPRM, and RFI, so we'll be trying to sort of provide you, the policy committee, some suggested response to some of the questions that she is asking on the governance side. That could lead into that September hearing and other events that we will be doing.

That's our proposed schedule of topics. Now the first topic we decided to address says here message handling in directed exchange, and that seems like really a mouthful. What that really is all about is what happens when two covered entities, two healthcare entities want to share data about a patient. That's what it's really all about. Message handling is a message is something that goes electronically from one healthcare entity's computer to another healthcare entity's computer. And directed exchange means that's occurring in the process of treating a patient. So it's sometimes easier just to give simple examples. An example is e-prescribing, ordering a prescription for a patient or ordering the laboratory test or getting a test result back or a specialist sending a consultation note to a primary care provider, something that just happens almost automatically as part of the process of treating a patient, but involves two different independent entities, not within an organization, but between two organizations.

And so the two questions we wanted to ask and answer, the first one is what are the policy guardrails for message handling in directed exchange, especially related to PHI, protected health information? The next one is who is responsible for establishing trust when messages are sent, which is actually a very interesting question? And to answer these questions, I was interested in Judy's comment about being like at a high level policy. One of the challenges we have in answering these questions is how high level a policy should we be, and how much sort of role or level, if that's a word, into the technology we should be? It's hard to find the exact right level, but this is a little bit more technical than the other presentations in terms of how we're responding to these questions.

The way we handled this for the message handling question is we first sort of established four categories of messages that are set, so this classification to four groups. I'll do my best to walk you through these. The first category says the message is sent or received, and there's no intermediary involved. And so the first question is, what in the world is an intermediary? And when we use the intermediary, we use that in sort of like a high level intermediary, so a third party. This is a health information exchange organization that we are talking about, or it could be an organization like say SureScripts that it's an entity that does something to the transaction, as it's in place. It is not a server, or it's not any of the wonderful stuff that exists in the Internet and sends messages around. That's what an intermediary is.

This first category is no intermediary involved. That just means that two covered entities, two entities are sending and receiving information. An example could be a cardiologist who has a private practice, but tends to practice almost entirely … hospital, perhaps a community hospital. Could very well have his office, computer system for his office, patients connected directly to the hospital because they're

exchanging information frequently. It could be easy to do if he's located in the doctor's office building on the campus of the hospital, which happens very frequently. But there are many examples of this.

Another example, a very simple example is a physician's office orders a laboratory test, and the EHR system has the right software and the message is communicated directly to the laboratory. The laboratory directly sends back the results. Many large healthcare organizations are doing this already. They're sending information back and forth. The messages are always encrypted. There's a basic assumption in all of these discussions, so that's the first category.

The second category is there is one of these third party intermediaries involved, but the messages are always encrypted. This occurs, this is an example that we'll talk a little bit more about in a minute, but could be a physician's office that says I want my local HIE organization to do this for me, so I'm going to send all of my transactions to Utah Health Information Network, and then it's going to go ahead and send it to whoever it belongs to for me. It'll take care of it for me, and I'll send back some messages. So that's an intermediary. That's the second category.

The third category is an example where the intermediary has access to unencrypted PHI, so this means that, in transit, the message for some reason or another, the patient becomes identifiable. Maybe just within the computer system, but the computer systems identifiable. And two examples of this would be actually NEHEN, the New England Health Exchange Network. What happens is, as the messages pass through that network, they actually open the message and check the syntax of the message to make sure it's accurate and correctly formatted. And if it is, they forward it to its recipient. If it's not, it's like return to sender. I guess that was an Elvis Presley song. Return to sender on the message, so I guess the song can come back into having some great meaning.

And the final example is the intermediary opens the message and changes the message body, either the format or the data in the message body. Actually, a simple example of that is the way SureScripts works where e-prescribing where a physician will do an electronic prescription. You send it to SureScripts, and SureScripts will sort of like rearrange the furniture. They'll move the data around. They'll perhaps change the code set. They'll change it from RxNorm to something else, and then they'll transmit it to the retail pharmacy in a format that the retail pharmacy's computer can read it, so that's the value that SureScripts is adding. But in doing that, they have to open the message. It has to be exposed to patient identity, and then it sort of moves the message forward.

These were the four categories. It's an interesting way, and important way to understand how we are categorizing it, but we do not do … one of the ways we could have approached this, we could have said we wanted to look at how much PHI gets exposed. In other words, which are the data elements? Is it 2D elements, is it 5D elements, is it clinical information, or is it administrative information? …claims clearinghouses? Instead we just said, as soon as the patient's identity is known, then you jump to another class. It doesn't matter what else you know about the patient. In fact, that could be the only thing you know. As soon as you know it, you jump to another class.

Once we developed these four categories, then we developed a policy recommendation for these four categories, which you see on the next screen. There's a recommendation that I ask you to comment on and approve, but the first two categories basically we're saying those are the ones that are the most likeable. We're saying that unencrypted PHI exposure raises privacy concerns. The real concern is that this intermediary will – what people are very concerned about will start collecting the data, perhaps reselling the data, and that that's its own world of interesting issues.

But because the first two models don't have those concerns or a better way of saying it, are less likely to have those concerns, because one of the things I'm looking at Latanya is one of the things that Latanya has taught me is when I presented those four categories, it's not necessarily the correct assumption that they're in an increasing level of risk. They each have their risks associated with them. But the first two categories where everything is encrypted, we are saying very clearly ONC should encourage that. That's very simple.

Model C and D where there's unencrypted data, we're saying as soon as the patient identification is known, basically that's sort of like a ticket to the world of the BAA, the business associate agreement, that basically you have to have some agreement with the third party intermediaries about a whole series of issues, but especially you have to establish clearer policies about to limit retention of PHI and restrict its use and reuse. On that issue, you can see this in the fourth bullet, our team, it says may, it's likely that we will make a further policy recommendation concerning retention and use of data really by these intermediaries.

Then we also have model D. It sounds like the model of a car, but model D also, which is the one where the intermediary transforms the data in some way, and it basically needs some contractual issues relating to quality and accuracy of the transformation. Then the last two … we also dealt with something that's called audit trails. Audit trails in this context is basically these organizations will keep track of the incoming messages and the outgoing messages. And that also, if that has PHI in that process, is an issue. That's the recommendation, and this is the recommendation that actually is very helpful for the people doing the work in NHIN Direct.

The second issue that we dealt with is this issue of trust. We translated this question of who is responsible to trust to who will establish exchange credentials. That may seem like an incredible intellectual leap. I don't know if cheetahs can leap, but if they can, we did it. I really don't know – I think I'm going to have to learn that whole area of biology or whatever.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Cake, to weeds, to cats.

Paul Egerman – eScription – CEO
…I'm a computer guy, so I'm just more used to … concrete. It's like the weeds, it's like I'm not used to that … but I'll think of something. I'll think of something to say that I should have said in about an hour in response to that.

Anyway, on this issue of trust, the basic issue here is the way we translate this is to say, well, to do all of this wonderful exchange concepts between covered entities, you have to know. You have to authenticate. The sender has to authenticate the receiver. They have to know, well, if I'm intending this to go to Dr. Calman, is that really Dr. Calman's computer? Is it really going to get to the right place? How do I know that that's the right place?

And so the way you do that is you have something called a digital credential, which is really like a certificate that's in effective given to the computers, not given to the entity. It's actually installed on the computer, so when the machines talk to each other they can validate that they are the correct machines. The question is, well, who is supposed to be issuing these things, these digital certificates, and who is really responsible for authenticating it?

We looked at a few models. One member of our team said, well, the government should do the whole thing. The federal government should issue it. The federal government should make sure that it's all

done correctly. We had another member of our team who reminded us that the Constitution has the Tenth Amendment, and that was a very appropriate thing to be reminded of, and so we recalled that.

In this slide, as we talked about, I think David Lansky talked about a hierarchical approach where the federal government does something, and the state government does some other things. But we actually ended up with going with a decentralized approach, and we have consensus on this. There's like a few bullets here. The first bullet says the responsibility for maintaining the privacy and security of the patient's record rests with the patient's providers.

We started that way for a number of reasons. One of them is you start doing all of these discussions about encryption and messages, and you start to lose sight of the fact that is really still about a patient and their provider. That's what it's all about, and it's the privacy of that interaction. So we wanted to make sure that when we did this whole discussion that we started there. And the other reason why we wanted to start there is also very simple is that's also a reflection of what the law says. Whoever holds the data, the protected health information, is responsible for maintaining the safety of it. That's also simply a reflection, so that's just a very simple way of a starting point.

Then we said, well, if you look at functions like issuing digital credentials or authentication, authenticating and verifying the provider identity, providers can do that themselves or, at their option, they may delegate it to some other organization. It can delegate that responsibility to an authorized credentialing service provider. So the idea is … what I showed you in the previous slide … four categories and there's a lot going on directly between providers already. The idea is, well, if they want to continue to do that, they can.

But if they want to, a provider can say, well, I want to delegate that, and I want to delegate that to this health information exchange organization, or possibly I want to delegate it to another provider. So maybe they want to say, I want to delegate it to Intermountain Healthcare, and that's a service we want them to do for us. We'll send all the messages to them. They'll make sure it goes to the right place. That would be another way one could do this. That was our starting point in this decentralized approach.

They said, well, you still have to make sure this is all done correctly, and these organizations are trustworthy. And we said, well, the federal government and specifically ONC then has a role, and they have a role in establishing and enforcing clear requirements and policies about the credentialing process, and those policies must include a requirement to validate the identity of the organization and individual requesting the digital credential. That requirement to validate means you've got to make sure that if somebody requests one of these, like it's ABC Pharmacy located on Main Street, somebody has got to make sure they really exist and they really are a pharmacy. And so we see the federal government has a role there.

We're saying the state governments can provide additional rules, but the state governments also have a big role in this process … state governments frequently are the ones who do licensing for these organizations anyway, so they can actually play a major role in making sure the credentials are correct. This is also a very important concept. Now putting forward this concept of a decentralized approach with the federal government and state government applying sort of rules, we're also saying this is a starting point because there are a lot of other issues that we may be going through in terms of issues like directory services, and it's possible we're going to come back to you and make some variations of this. This is actually our second recommendation that we were asking for you to approve is this concept we're putting forward here of exchange credentials.

Then we also had one other topic that we discussed, I just want to review with you briefly. In a meeting actually … Tuesday, there was a recommendation that was initially made directly to the NHIN Direct team that their technical model should not involve intermediary access to unencrypted PHI, which means it has to be either in model A or model B of two of the four categories. And we thought we had consensus of that when we had the meeting. However, this happens sometimes when you start to write it down. We realize we didn't have consensus, and so what happened was we actually three different issues.

One was there were some technical people that said, well, there is some levels of unencrypted data that has to occur, that you can't quite fit it into A and B, and so we had some discussion about that. There was also a discussion of whether this was directed to something called simple directed exchange or not, and there were some issues there. And there was actually also an issue that Latanya had raised earlier. I don't know if she wants to speak to it later, but she actually expressed concern that perhaps we shouldn't be making recommendations specifically around the NHIN Direct projects efforts, that we should be sticking to generalized framework recommendations.

I put this forward not asking for your approval, but also simply to tell you about it. It does illustrate a number of things. That's the first thing I want to tell you, but I also want to make sure I put it forward because there are members of our team who feel very strongly about this. There's a lot of passion about these issues, I mean, a lot of passion about these issues.

Latanya Sweeney – Laboratory for International Data Privacy – Director
And not just me.

Paul Egerman – eScription – CEO
Not just Latanya. There's a lot of passion on these issues, but it also shows this is hard stuff. This is not easy. As I say, it's hard to find the right technical levels. It's just like, and I can't do a cake analogy, but it's like is the porridge too hot or too cold. It's hard to find the right level, but as you do that, sometimes you realize later, well, gee, if we had gone a little further, this doesn't quite work right. That's why I show that, but anyway, we have the two recommendations that we asked you to comment on, but having mentioned you, do you want to add anything to this, Latanya, in terms of what I just said?

Latanya Sweeney – Laboratory for International Data Privacy – Director
First of all, I have to commend you. You guys did an incredible job. There are some meetings … just half a day sometimes, and you kept them focused, and I thought you just did a fantastic job. I think the fact that you could take a complex issue and bring a group of people together and actually come out with a document where you can make these statements in less than a month is a pretty amazing accomplishment, so many thanks to you.

But I need to say about it is that the recommendations and the discussion are all rooted around one class of technology solutions that have to do with message passing. People like that because it's easier to understand. It's like faxing and so forth. The metaphors are all there, e-mail and so forth. But from a technology standpoint, you're literally … way down, way down in the grass, and so even though you brought the group together and … process and … necessary, the recommendations themselves are still rooted in the concept of message passing.

Then that, of course, directly correlates with NHIN Direct, and then the question of making direct communications with NHIN Direct is really odd because we did a survey, and there were about 50 companies around the country who have invested millions of dollars in NHIN solutions. And there are tons of communities around the country who are making technical decisions when presented with these technologies, and none of those technologies have the benefit of having gone through the exercise that

NHIN Direct…. NHIN Direct is a crowd source effort, so we recognize that people are … but on the other hand, you know, some of them work for companies or have company interest, and so there seems like a kind of unfairness in the process, both in the fact that NHIN Direct is sort of first-class vantage point where people who spent a lot of – some of them are small companies who have incredibly great, brilliant ideas, but can't get an hour of anybody's time at ONC, not the fault of ONC, but just the realities.

And so, and then others are large companies who have invested a lot of real estate in developing this stuff and … it and getting it perfected in a sense, and they also don't have the benefits. I do think that there are two problems with it. One is this over-fitting to NHIN Direct so that the policies that have come out only in the message passing space, and all of the other brilliant, innovative, incredibly wonderful solutions are totally orthogonal to these recommendations. And so that bothers me, and so I'll just stop there.

Paul Egerman – eScription – CEO
I see … wanted to say something.

Joy Pritts – ONC – Chief Privacy Officer
Yes. We find ourselves in a very difficult position just in general in this whole area where we are under extreme tight deadlines to have solutions available for people to meet their statutory deadlines for meaningful use. One of the means that was developed to address some of those issues was NHIN Direct. They were proceeding, and they had asked us in specific for some policy guidance along some technology choices that they were going to make.

Faced with the choice of letting them go ahead without any input from the policy committee in making those choices and focusing on those, at least in the short term, they were very interested in getting the input from the policy committee on their choices before they made them, and so it may not be an ideal situation, but I think that we were able to assist them in this process. Now, having said that, it was when this group was considering the NHIN, well, in particular, they're trying to address directed exchange in a means that would assist NHIN Direct. It was a difficult line to draw whether they … whether they were trying to just recommend about NHIN Direct or directed exchange in general. They did try to reach some and did present some recommendations that are broad enough to encompass directed exchange in a broader fashion.

It is, as you note, a subset of all the issues that have to be determined, and the group, that's how a lot of this work is done. It's done in little bites, usually at the end. It's not presented until they resolve all of the issues, and at the end, you get a whole package that's wrapped up in a little bit of a bow. We didn't have the luxury of doing that right now, but we do have, with the tiger team in particular, time at the end of the summer to go back and look at all of the kind of interim recommendations that have been made to make sure that when you put them all together, they make some more sense, and that they make sense and are fairly consistent across the board, as you're looking at different models of exchange.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
David asked me to facilitate this piece of the discussion since we're going to be making recommendations to him ultimately.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Thank you.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Can I clarify what you're ask is of the committee? You used the term two recommendations. That must be applying a software group of some sort, so the first set is to understand the A, B, C, D, and say let's move to A, B, and defer on C, D. Then the second one is we need to have some kind of exchange credentials. Have I understood…?

Paul Egerman – eScription – CEO
The first group is what you see there. It was not to defer on C, D. There are recommendations…. In other words, I understand why you say that because there's a place in the recommendations that we're going to make more recommendations in one area. But this does make recommendations for all four: A, B, C, D. And so this is, when I say two, this is one of them. The other one is the exchange credentials. Those are the two that I'm looking for.

M
Can I ask a clarification on slide one, which is, let me talk software to you. Is there a C++ here? What I mean by that is you talked about C as being unencrypted PHI. There are other things that … the public databases and statistical processing that Latanya partly raised can give you, even though it doesn't look like PHI, can lead to PHI with additional information. Did you consider that?

Paul Egerman – eScription – CEO
To me, that's a totally different category of issues. In other words, this is really all about a message going between two covered entities, and it's all about message handling. You raised interesting issues about can you sort of like re-identity de-identified data, for example. That's an interesting issue. That's an interesting issue that we may address later, but it's not a message handling issue. In other words, this is just about sending the messages, and it's like the comment about the Elvis Presley song, which is the song about the guy who sends a letter to somebody he cares about, and it comes back to him. But it's just like the mail, the letter metaphor is actually a good one. This is a message going from one entity to another without the treatment of a patient … framed it that way.

M
The issue comes in because C and D involve the use of intermediaries. There may be business associates who carry on the message carrier function, but one could siphon off information that appeared not to be explicitly identified and create re-identifiable information. That's where it can enter into this discussion.

Paul Egerman – eScription – CEO
That's correct, and that's why you see in the bullets, the one that's sort of in the middle. Pardon me?

Latanya Sweeney – Laboratory for International Data Privacy – Director
It's the last one.

Paul Egerman – eScription – CEO
The last one? Yes, intermediaries that support models C and D require contractual agreements in the form of business associate agreements that set forth applicable policy and commitments and obligations, but it's also … we're going to make further privacy policy recommendations concerning retention and reuse of data, and we haven't gotten that far. What you say there is the key issue. In other words, the four categories, A and B is fine. As soon as the information, the patient name gets known, people get very worried, and they're very worried about exactly the issue that you talked about, which is, will the data be retained, perhaps surreptitiously.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Other comments, questions? David?

David Lansky – Pacific Business Group on Health – President & CEO
I'm just concerned with how the recommendations get framed. It seems to me like C and D today constitute the vast majority of transactions and where most of the value comes from in terms of exchanging things. We don't really have, unless I'm not thinking about things in the right way, that much of A or B going on today. Is that accurate, do you think? If it is, I just think it's important that the recommendations make it clear that we expect that there will be a lot of C and D going on, but these aren't necessarily bad things.

Paul Egerman – eScription – CEO
It's a great question, David. The first part of the question where you say, is it mainly C and D, is that accurate? I don't know. I do believe that there's a lot more in the first category than we realize. There is a lot of that already going on.

Latanya Sweeney – Laboratory for International Data Privacy – Director
I did bring up, and I think that did have an affect of us backing off of saying … best practices. I postulated that the … exactly the reviews. Even in the space of message handling, that what I can do in this space with B is more useful than what I can do if I go backwards. And so as I try to … so the thing about best practice, you've got to put the two against each other.

David Lansky – Pacific Business Group on Health – President & CEO
That's right.

Paul Egerman – eScription – CEO
That's exactly right, so we're saying A and B is something that should be encouraged by ONC. But we're not saying that C and D are bad. In other words, that's not the intension is to say they're bad because indeed value is being added, so it's almost like….

David Lansky – Pacific Business Group on Health – President & CEO
Right. That's really what I was getting at.

Paul Egerman – eScription – CEO
Yes.

Gayle Harrell – Florida – Former State Legislator
What I'd like to add to that also is that when you get to C and D, your level of policy has to rise, and the perhaps requirements, you had that level of trust that you have to incorporate in the public. When you get to C and D, it's very important that we have very clear, specific recommendations as to how you protect that information, and the responsibility of the people that are doing C and D comes to a different level. So you can say A and B is a directed exchange, entity A to entity B, and they are there, and there's no intermediary. There's no touching. It's no PHI. That's fine. You can let that go with certain degrees of accountability. You have much more degrees, higher degrees of accountability when you get to C and D, not that it's wrong, bad or whatever. You don't want to say good or bad. It's just that there are higher levels of responsibility required when you get to C and D.

Paul Egerman – eScription – CEO
That's a good point.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO

Coming back with more, that's what bullet three says, right?

Paul Egerman – eScription – CEO
On those issues.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Yes.

Paul Egerman – eScription – CEO
Reuse and retention, we will be coming back with more because it really … at least in my opinion. People might … there hasn't been a lot talked about that issue, but it does raise the whole issue of what was presented earlier too of governance because the data has a lot of value. By value, I'm talking about financial value to an intermediary. And so you have to not only set policies, but you do have to have a governance approach associated with it.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Art?

Art Davidson - Public Health Informatics at Denver Public Health – Director
Thank you. This is a pretty complex topic to really get our hands around. If we go back to the discussion that we had earlier this morning with Doug and Mary Jo, am I understanding that we're now taking a use case that's just around the directed message exchange and that the recommendation from earlier today was that there be additional use cases that we suggest as a policy committee. Charles brought up earlier the idea about research and the whole opportunity here about this reuse. So at this point, we're not trying to address anything more than this specific use case, and we're doing what ONC is asking us. Is that right, or are we putting off until later? Are we not thinking that this is something that we will get to?

Paul Egerman – eScription – CEO
It's a great observation. What we're doing is we're looking at this, what you call a use case, as you might call it a base level case is the first step in the process. In other words, this is not all we're going to do if you went back to the schedule. This is what we're trying to do now in the first few days, possibly in July. Then we're going to go do a lot more other cases. In other words, we'll be back in July. Hopefully Deven will be back in July, and we'll be talking about some of the more complicated issues. With other communications that are being raised, it's interesting that this one that we felt was the base case, we realize how unbelievably complicated it is. The next ones will be harder, but we will be coming back with those.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
David?

David Blumenthal – Department of HHS – National Coordinator for Health IT
Marc first.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Sorry.

Marc Probst – Intermountain Healthcare – CIO
I'd have gone to David too. I'm just not sure I'm comfortable in that first recommendation where it says under A and B that ONC should encourage the use of that model. I certainly can see where ONC should point out the benefits of that model around privacy and security, but because we don't fully know the

benefits of C and D, of we haven't flushed that out, I don't know. It just seemed a little too definitive to state that we should be encouraging the use of A and B, or that ONC should be.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
David?

David Blumenthal – Department of HHS – National Coordinator for Health IT
So I wanted to just make a contextual comment for the benefit of the committee as they go through this because, as you look at that agenda of items, this is, to some degree, child's play compared to what is going to come down the line later. And yet it is proven difficult for the committee to get rapidly to consensus, and one of the most difficult issues that this committee and the Office of the National Coordinator will have to deal with is this set of issues. We've got a pretty good record of getting consensus on recommendations, even on some pretty complicated issues up to now. But as a matter of process, I'm not at all sure that lacking urgency and a sense of needing to make decisions and, therefore, being willing to compromise on sometimes strongly held principles, that we're going to be able to get to that level of consensus on these topics because people feel passionately about them.

I guess what I want to do is simply say that we have constituency stakeholders who are knocking on our door loudly asking for advice. They would love in some cases to have us tell them what to do, even though we don't have the authority to tell them. But they would love to have us tell them what to do. There are many states that are wishing for ONC to say exactly how they should resolve some of these privacy and security issues. And so we will, the ONC will have to make some of those decisions, and we really would love to have your consensus advice about that, but I don't know whether you all would eventually feel comfortable giving it to us. We'll have to see, but in the meantime, I would just ask you to keep in mind the time urgency that we face, the need for states to begin to be active in creating exchange capabilities, the need for providers to have some confidence about when they can and cannot exchange information and under what circumstances.

There is a history of other individual states and communities and other nation states getting to agreement on these issues. It usually takes some time, more time than we likely will have. So as in everything we do, we are going to be moving more rapidly than would be ideal, and we'd just love to have you stay with us, but we'll do what we have to do in any case.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Thanks. Latanya?

Latanya Sweeney – Laboratory for International Data Privacy – Director
Yes. I just wanted to say I think I'm the only computer scientist here. It's been really, really frustrating because, as a computer scientist, we deal with these kinds of complexities all the time, but we will start with what are the requirements. We start with meaningful uses. We'd say … in the space of technical solutions, and we could make properties about them, and we could rule out or identify quickly the spots. We realize that computer scientists don't run this process and computer scientists don't really have a voice in this process really. And as a result, that's why I understand that you take this approach of being down in the weeds. But … way down in the weeds like that, you're making it really, really hard. And you're making recommendations that even around the table were saying, but what about these other things that are going on. They're not accounted for that.

Even Tony could say, what about all the meaningful uses. And then there's this confusion between what's a use versus what's being … with what's a technology. So uses and technologies, those are different axis, really, and so speaking of more uses, if we're going to put in a message handling, we're still

going to stay way down here. And I think you're really making it hard. And I think, in the end, you are going to have to make some hard decisions that are not going to be anywhere near optimal.

The beauty of this over anything that you ever had the opportunity to do, over anything Canada ever had the opportunity to do, over anything and all of the problems, the technology, privacy clashes that I personally have witnessed in the United States, including the total information awareness, all of those for which I've had a front row seat. What makes this different is that you actually can design the technology. You can actually change the whole discussion and really have a much lighter weight discussion and have utility with privacy as opposed to forcing that kind of debate. It's almost inevitable that what you're going to end up with is utility or privacy, and that's really a false belief that these two can't coexist.

It's particularly, and what controls that is the design of the NHIN. That's what controls the tension. And if you keep the tension way down low, you're going to keep it really tight. If you come up and think of innovative designs or look at the kind of things that people are proposing, you're going to come way high, and that tension is going to get a lot less. But in some sense, the way you're approaching it is dictating already the difficulties that you're having.

I know I've said this before in different ways. I just thought I'd just have to say it again. I reserve the right to maybe say it again in July.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
So noted. Charles?

Charles Kennedy – WellPoint – VP for Health IT
It's hard to follow that comment, but I wanted to reinforce what Marc said about expressing a little bit of concern about preferring options A and B, primarily in part because I think that a lot of the value that potentially can be delivered is with C and D, and just to your point about kind of value versus privacy, I see that. I'll give you an analogy with the administrative world. Right now, there's hundreds of millions of transactions that go through clearinghouses on the administrative side. In fact, they do unpack the message and check for things like data elements that should be filled out and other things that make the quality of information flow much better. I'm a little bit concerned that if we kind of prefer a model that doesn't allow those kinds of things, what you open up at the other end, I'm not sure it's going to have the quality and the value that one would like.

Paul Egerman – eScription – CEO
Excellent comments. This discussion is fascinating because the discussion that some of the people had on Tuesday was like 180 degrees different. So if you look at my last slide where I talked about the thing I called the discussion that I did not propose as a recommendation, there were some people who were taking the exact opposite approach. They were saying NHIN Direct and ONC should only play in the A and B space. And feel very adamant about that.

And if one of them were here—I don't want to put words in their mouth—but the way I think they would respond to your comment, Charles, about the claims clearinghouse is they'd say, well, the existence of a clearinghouse simply shows the failure of our standards efforts. It shouldn't be necessary to do that. Everybody should be using the same standards and the right standards, and so you shouldn't need to have a clearinghouse. That is what they are saying, which in some sense has a great deal of validity to it.

I mean, if we did things right, we wouldn't need those intermediaries, but the problem is we're not there, and so the way this is drafted by saying it should encourage A and B is we're sort of saying we want to

head in that direction. It's not like requiring us to be there. That is the way that this is drafted. The last discussion was to require us to be there, and that's the thing that we run into some issues.

Charles Kennedy – WellPoint – VP for Health IT
That's a perfectly fair point. I was just trying to use that as an example for the notion of value versus privacy.

Paul Egerman – eScription – CEO
Yes, which is a great discussion too. It's also, that's a critically important point. I mean, identifying patients unfortunately occurs all the time. You know, since I'm talking to you, I'm giving the administrative example, but almost every medical group or many medical groups use mailing services. They print all their statements at the end of the month, and they take it to some company, and the company folds the documents and puts it in an envelop for them, and maybe even puts postage on the envelope. Clearly that's exposing PHI, but people don't worry about it. They feel, well, you've got to choose the right mailing service, and you're going to throw it all through the machine anyway, and the machine actually makes a hell of a racket. It's a really amazing thing to hear when they fold those things, so some people would say, this happens all the time, and so it's an issue, and it's also an issue, an example of one of the challenges that we have.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Judy, another computer scientist at the table.

Judy Faulkner – Epic Systems – Founder
Yes. A little bit about practicality, I think, versus perfect world. If we're going to send information back and forth, A and B, directly get there and get it there quickly, and can do it with less cost, and can meet the timelines I think that we set. And, Charles, I think your comments about additional value to having a clearinghouse that can do other things with that data is there. But then what is the point? Is the point to get it back and forth, so the providers can care for the patient, or is the point getting more value out of that data through other groups that can get value from that data, which I think also goes to yours, Art. What can you do with the research side of it? I think somehow they're all getting mixed together in there.

A similar thing on practicality with respect to what Latanya was saying, again, I think everything could be rewritten. It's always, in computer science, given enough time and enough people, you can do almost anything. But then we again have the dates that we have to make, and the healthcare of the people who need care, and I relay that there's a theoretical versus the practical that we have to evaluate as well.

Latanya Sweeney – Laboratory for International Data Privacy – Director
…I would just say that in the same month had taken the other approach, you know, as you start off with engineering requirements and analysis, what you basically get from the meaningful uses is sort of already done, and you survey the technology. In one month, you could still have a document like this, but it's not that it's a message passing. It would be much more up in the trees. I would say it's a time issue.

Paul Egerman – eScription – CEO
Yes, although I do hope, Latanya, our next document is more up in the trees, as it were, for a lot of reasons, not just because that's where cheetahs belong.

Judy Faulkner – Epic Systems – Founder
The thing that I would like to know is some of the forest, which is what are the timelines for deciding is there going to be national ID. What about segregation of data versus opt in and opt out? What about the companies that have standalone PHRs, and what are the rules on them, and what about the reuse of

data for different purposes? Those more high level things, if we're down in the weeds, when do we get to those?

Paul Egerman – eScription – CEO
Hopefully July.

Judy Faulkner – Epic Systems – Founder
Okay.

Paul Egerman – eScription – CEO
Really, I mean, June 29th, we have the patient consent hearing.

Judy Faulkner – Epic Systems – Founder
We better have a lot of good fishing lines to pull the fish out of the weeds.

Paul Egerman – eScription – CEO
Okay. I'm just really having trouble following metaphors, the cake and the fish and everything. But we'll do our best.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
David?

David Bates - Brigham and Women's Hospital - Chief, Div. Internal Medicine
I just want to comment that I'm not convinced that A and B are necessarily cheaper, at least from the healthcare system perspective because you may be sending around information that's dirty or unintelligible. Level C, for example, which used as NHIN has driven down that cost of claims, processing a claim from $6 to $0.60. There's a very big return on investment associated with just moving things around and then checking to make sure that the things that Charles mentioned are there or are not there. If they're not there, then they go back. I just think that should be an open issue.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Since we come to the close, are the any more questions? I think what I'm going to try to do is talk about the two lumps of recommendations or statements separately. I think what I've heard, to distill the comments, a lot of pushback in terms of whether there is a judgment about whether there's the value proposition of models A and B versus C and D. If I interpret the way you said in terms of ONC should encourage the use, I think what you're saying is that it is easier to discern policies when dealing with A and B, and that you promise to come back with additional policies that would help insure the safety of using models C and D in the next month, as you wrestle with all of the weeds and trees. Did I get that correctly?

Paul Egerman – eScription – CEO
Yes.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
And would that be a proper interpretation of what they said when you want to weigh the value? Okay. So what they said was encourage, it's really saying this is an easier thing to deal with from a privacy and security point of view.

Paul Egerman – eScription – CEO
One way to address it, if you want me to just take that sentence out.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
You did mean something with it, and perhaps it's just worded differently, so that's why I tried to explain what I heard.

Paul Egerman – eScription – CEO
The privacy issues--

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Are more straightforward.

Paul Egerman – eScription – CEO
--are more straightforward.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Without putting a value assertion on that. Okay. With that clarification and what they meant with that sentence, does the group feel comfortable with this set of statements on this slide? All in favor?

W
Aye.

M
Aye.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Any opposed or abstain? Okay. Good. Now moving to the second set, which is, there needs to be credentials for exchange that's to understand who is on the other end of the line and what authorities and trustworthiness do they have. Have I captured that sort of – is that what you meant by this set of statements? Okay. Do people have difficulty with that? All in favor?

W
Aye.

M
Aye.

M
Aye.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Any opposed and abstained? Okay, Mr. Chair. I think we have two recommendations headed your way.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Wow.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Two sets.

David Blumenthal – Department of HHS – National Coordinator for Health IT
I have a recommendation without a metaphor. It's called lunch. So we'll see you back in a half an hour.

Judy Sparrow – Office of the National Coordinator – Executive Director
We're ready to begin. Thank you.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Ladies and gentlemen, colleagues, boys and girls, we're really – we've got honorary Dr. Chopra here.

Aneesh Chopra – White House – CTO
Yes. I just promoted my … recently apparently.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Here to tell us about, for those in the know, the 1561 activity. For the rest of us, it is the responsibility for the policy committee and the standards committee to help the health reform effort by thinking about enhanced IT enabled enrollment capabilities. Aneesh, welcome, as always.

Aneesh Chopra – White House – CTO
Thank you, David. What I'd like to do over the next 15 minutes, maybe less, is provide for you the context about the group's charter, its guiding principles, and the early work that's come out of our very first meeting that happened maybe 10 days ago. As David mentioned, the underlying philosophy is, as we welcome 35+ million Americans into our new system, we want them to experience the 21st century economy, not the 18th, 19th, or 20th century. As I'd like to say, we don't want them standing in line at the DMV when they experience this. We want them to experience something that reflects the spirit of the Obama Administration's commitment to advancements in information technology.

Here's a quite background on the folks that we've sat around the table. I'm not going to go through all the names, but I want to highlight, this is truly an all hands on deck model. We have the traditional folks who are engaged in enrollment software and insurance industry perspectives and other folks representing kind of the government and the public programming areas, but I'm also excited to report, we have brought around the table folks who are out of industry who understand sort of emerging models in data sharing and data standards that could help bring some perspectives to this environment, and you saw that in our first meeting where we had a really lively exchange where the kind of entrepreneurial crowd hadn't been as exposed to the challenges of our public sector, human services programs, and vice versa, and that combination really led to a very healthy discussion.

I'm also pleased that we've got a robust list of federal partners at the table, not just the traditional ones, HHS, IRS, and so forth, but actually stakeholders from across the federal government that could contribute to this conversation. So very pleased with the quality of the team and would happily engage in conversations about process. I won't read this slide, but this is the legislative provisions of the Affordable Care Act that highlight the fact, as in all of our work, we have to do it yesterday, and it's got to be world class. And I know we're not that unfamiliar with that assignment more broadly, both on the policy and standards committees.

What is the specific charge? What we're going to do is currently inventory the standards that are already in use, so there are examples where states and localities are verifying and enrolling customers, if you will, using electronic platforms, so what are the standards that are in use. What are the gaps based on what the requirements are coming out of the Health Reform Act, and how might we develop a set of processes to get the gaps addressed, if you will? We're specifically focused on the following area: electronic matching across the state and federal data, retrieval and submission of electronic documentation. This is very important for verification purposes. We'll get back to that, I guess, a little later. The reusability of eligibility information, the notion that you shouldn't have to repeat yourself 100 times, which is obvious to

everybody, but not as easy in the real world. Making sure that individuals can maintain their eligibility information in a place that's accessible online, and obviously to be somehow proactive in the notification regime on eligibility where possible.

Now the deliverables that I was alluding to, we will have a thoughtful inventory of standards based data exchange that are currently in use. We will have some candidate standards for data elements at the data atomic level, so it doesn't really matter what you're underlying software systems are. If we kind of know you need to validate your residency, or you need to validate, you'll hear that in a minute, what those data elements are, how we can identify for candidate…. And then a process to fill in the gaps to rapidly cycle those requirements into working prototypes and live implementations so that we are prepared for the 2014 environment.

There are some potential candidate standards that we've already discussed in our first meeting that is the core data elements everybody has to know: who you are, where you live, your income status, your citizenship status and so forth. The messaging standards about eligibility and enrollment tracking, consumer matching across systems, making sure that we have the ability to send and retrieve verification information around those key questions that are, in many cases, sourced at the federal level. And then how we actually communicate the enrollment information. Do we have to mail you a letter, or can we find electronic means to communicate that information and up and down the information supply chain? Obviously, like in everything that we've got to do, how we make sure that there's privacy and security provisions built into the transport layer and onto the authentication side.

Our challenge here is to conceptualize standards that are going to be useful across a variety of use cases or architectures. Now this is an important point, and I'm going to hit this time and time again. We are the technology sector. We are in service to the policy objectives. We are not describing the policy constraints, and I think this is a very, very, very important point we come to time and time again.

As we have a conversation about what 2014 looks like, what are the rules of the road, how our federal agencies will interact with states and localities with the proposed exchanges, there are a whole range of policy questions that are emerging. This committee is absolutely not the place to engage in that debate. We certainly learned a lot in our first hearing about the kind of options that are on the table. But what we want to do is support a wide variety of use cases. At the end of the day, if you have to know the person's name, whether it's done by a front-end, consumer-facing portal or a federated query across a number of locations through federal exchanges, state exchanges. At the end of the day it's who am I, where am I living, what do I need, what is my income status. That's the key set of requirements.

We have a set of policy principles that we've put here. I think this is a match up, if I'm not mistaken, of policy principles for the standards committee and the policy committee, so they all look the same. Consumer at the center, we want to make the enrollment process less burdensome and simplified. Enter the information once and reuse. Obviously make sure that it's easier for consumers to move between various programs with all our eyes on the prize 2014.

On the standards committee side, these are the principles that we had agreed to in terms of the design of standards. It's worth repeating for this group. Keep them simple. Don't let the perfect be the enemy of the good enough. My third one is my favorite. Keep the implementation costs as low as possible. We're not interested in the massive, unfunded mandate burden of 2012, 2013, 2014, 2015, and 2016 that have massive costs associated with what we hope to be a simple process. So how can we build cost effectiveness into the design framework at the outset?

Then obviously this is not about a one size fits all standard. Given all of the complexities between state, federal, and local and private sector assets, we've got to find a way to be flexible, but again, adhering to the core message data elements, the messaging standards and so forth. Did I just mess that up? I think that's it. Yes. Okay. That's the full monte.

Where are we now? We had our first hearing. All of our hearings are open to the public. We had testimony from a whole range of policy advisors on where we are with respect to 2014 implementation to examples at the state and local level where they've already begun developing enrollment standards to how people are using the emerging, Web-based protocols to support these local programs. And we had a healthy debate about what the next path forward is, and that means I think Monday is our next meeting. We are going to have a candidate prototype use case that will try to bring all of this together so that we have a very thoughtful way of engaging moving forward. I wish I could tell you that use case. I'm not so sure we are legally allowed or whatever the rules are. But Monday, it will be revealed, and you're all welcome to seek comments or participate in that conversation, and I will leave it at that. Dr. Tang, where do I go from here? What do you need?

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
…questions and comments from the committee. While people are preparing, one of the things we talked about at a prior hearing and then this morning is the need to reduce disparities … healthcare, but … just in all government programs, you want to reduce or eliminate disparities. Amongst the demographic information, do you intend to collect … one of the things we came across in our hearing on disparities is sort of a … proposal from 2009 talking about more granular levels so that you can stratify and tailor programs and eligibility more precisely. Is that part of it?

Aneesh Chopra – White House – CTO
Great question. I think that may be the kind of thing that's worthy of getting testimony on, which is, we have data elements at the atomic level in the world as it is today. There is this desire to see what 2014 will look like, and you're describing a world where, in support of that vision of 2014, there may be newer and better data elements. That's the kind of testimony we need to capture, and we might make sure that the same folks who gave that testimony to you are engaged.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
I'll connect with IOM. That would be a good one because they refer to this as well.

Aneesh Chopra – White House – CTO
Yes, and I might add before I say much further, Paul is a very active member of our debate, so while he's having a huddle, can obviously come and talk…. We're all good. If you want to compliment or … what I said wrong or any of the sort.

Paul Egerman – eScription – CEO
Terrific job, Aneesh. It was a great summary, and … comment what Arthur was just asking about because he asked … that you just presented to what actually I had talked about just prior to lunch. It's a very interesting issue. First, it's easy to get confused in the terminology because you were talking about issues that are called HIEs, health insurance exchanges.

Aneesh Chopra – White House – CTO
Sorry … my slides … and it was the wrong one.

Paul Egerman – eScription – CEO

Yes. I just want to make sure everyone understands these are health insurance exchanges. This is a situation where the small businesses in the public can buy insurance from organizations that are basically state entities, and so when we talk about enrollment, what we are talking about is getting people from various social services enrolled in their health insurance exchange to make sure they're aware that they could get health insurance because they may not be aware that they're eligible for it, or they're eligible for subsidies, and it's an absolutely fascinating issue. It's … industry, almost like … is a different aspect. It's probably closer to the world that Charles is familiar with in terms of, at a very early part of the entire process in terms of how you enroll an individual.

Aneesh Chopra – White House – CTO
By the way, every hospital pays some ungodly sum of money to people to help bring in Medicaid eligible, the uninsured, screen them, so I actually think the healthcare system has seen a lot of this. They may not have the people working on that problem, typically in the finance department, engaged on these policy discussions. And one of the questions may very well be, how do we get the finance department that funds a lot of that consulting work to get people enrolled to get those requirements in so that we're smarter about it.

Paul Egerman – eScription – CEO
And … the case, Aneesh talks about sort of like this one stop shopping, and you apply for everything, and somehow even if you walk through the wrong door, it's still the right door, and you can get enrolled. It'd be nice at some point to really understand how this relates to the world, but we … most of the time … what we do with the insurance in enrollment is totally and completely separate from the rest of the healthcare system, and it doesn't really need to be that separate. But it is totally and completely separate.

Aneesh Chopra – White House – CTO
Yes.

Gayle Harrell – Florida – Former State Legislator
Thank you. Coming from a state perspective, I can tell you that at the state level, this is a real issue, and you have not just whether it's Medicaid eligibility, whether it is food stamps, it's a variety of things. The states are the ones that truly bear their responsibility down and are trying to implement a lot of programs. Is your anticipation that once you set in place these certain standards that states will be, that this will all roll out, and states will then integrate into a system where you can do eligibility for Medicaid? You can do eligibility for SCHIP. You can do eligibility for food stamps. And as well as insurance because, of course, under health reform, it is truly the state's responsibility to do the exchanges, and how each state implements that may be somewhat different, but it falls to the states to do that.

Aneesh Chopra – White House – CTO
That's exactly why I made the comment that technology is in support of policy, not the other way around. We do not know how all the machinations will work between who is running the risk pools, the federal, the state, how these things are designed state and local. I came out of Virginia state government. Our system has its own peculiarities, so rather than try to say this is a difference, as Farzad and I like to say, the nouns versus the verbs. If our process was to establish a big monolithic noun, this is the set of standards for enrollment. Thou shalt plug into the big brain. I think we have failed miserably. That violates every one of these principles.

If on the other hand we were to say, look, regardless of how you're technically going to do it, somebody is capturing name, and somebody wants to validate that that person lives in New Jersey. And the process by which you validate that, whether it be a communication with the Department of Homeland Security or

the e-verify system, or you want to conform that the person who claims that they're on CHIPRA can actually, you know, for the SCHIP program, can get that validated by the SSA. Those kinds of scenarios where you have a piece of data that should move from party A to party B for the purposes of validating or verifying in this case certain pieces of information. If we can make that system simple and easily adoptable, then however you want to go about doing it. You want to incorporate that into your existing systems? Great. You want to get new systems that can do all this stuff out of the box? Great. Whatever the circumstances are, it should support multiple flavors, and that's, I think, the design constraint we're working under. And we have all these stakeholders at the table, including the chairman of the NASIO and all this sort of stuff.

Gayle Harrell – Florida – Former State Legislator
May I follow up on that one? Certainly at the state level, you also then have the integration of other systems that will receive that.

Aneesh Chopra – White House – CTO
Yes.

Gayle Harrell – Florida – Former State Legislator
So is your goal or your vision of where you're going to allow … justice to plug into that? Where are you going? How far are you going?

Aneesh Chopra – White House – CTO
Let me just give you an example that I'm not trying to get ahead of the process we just started, but I just want to give you an example. The United States Postal Service has created an API to verify someone's address. They just made it a simple, technical call. Anybody could adopt that API, whether it's the Department of Juvenile Justice or Amazon.com or Timbuktu, whatever. And all that happens, you know, as you do this today, my wife and I, we shop online. So when we purchase something, often the screen would say confirm your information, and when you hit the button, that product, that vendor has triggered a service call out to the U.S. Postal Service, and spits back, well, according to the postal service, Aneesh, when I was in Richmond, I lived in Unit #1, and the postal service had me as unit #101. And it would come back and say, are you actually at 101? Click here to confirm.

Now when the postal service designed that API, they did not presume how and in what manner this would be consumed. It could be big systems consuming it. It could be a startup that would access it. They had to keep the design simple and easy to replicate. That is an example of a simple way to transmit the question of an address or application call to the postal service.

Now I don't know I we can do that across all the agencies and the mechanisms. We're going to learn about all of this as we get into the capability of the services that are needed for these scenarios. But in the world in which you're describing it, it would be tragic if only a certain box set of organizations could connect, but the same transaction that's needed in all these other scenarios can't. I think that would also be afoul. So again, coming from the state perspective, I am super sensitive and aware that there are a number of reasons why you'd need to do the same address verification example, whether it be in the human services program or beyond, and we need to make sure that that's an understood part of our process.

Gayle Harrell – Florida – Former State Legislator
With that then comes very specific privacy issues.

Aneesh Chopra – White House – CTO

Sure.

Gayle Harrell – Florida – Former State Legislator
And it opens up a whole other level, especially when you go into things like SCHIP with children.

Aneesh Chopra – White House – CTO
Sure.

Gayle Harrell – Florida – Former State Legislator
We go into things of juvenile justice, all kinds of things of that sort. And different states have different requirements.

Aneesh Chopra – White House – CTO
Sure.

Gayle Harrell – Florida – Former State Legislator
So there is a whole plethora of issues that will have to be discussed and the devil will be in the details, as we all know, when you get into these kinds of issues, especially on the privacy issues.

Aneesh Chopra – White House – CTO
I'm a glass half full kind of guy.

Gayle Harrell – Florida – Former State Legislator
I am too.

Aneesh Chopra – White House – CTO
We will get there. And the reality is, we already do electronic exchange in a lot of these areas. It's just that they're not done perhaps at scale, in a manner that's easy to adopt, in a manner that's got all the protections and provisions we want, so we're going to learn a lot as we go through this process. We already heard testimony for completely different models that are being used by the IRS and models that are being used in other areas, so absolutely we're going to have to pay attention. That's why we have a number of privacy officers and others at the table, and I'm clearly confident Joy over there isn't going to get away scot-free on these issues because we have to get it right. But we're in the first inning, a ways to go, but all that you've said has been absolutely critical to the work we're going to do.

Gayle Harrell – Florida – Former State Legislator
Thank you.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Charles?

Charles Kennedy – WellPoint – VP for Health IT
Hello, Aneesh. In the existing individual market where private health insurers sell health insurance to individuals, they're medically underwritten, usually, and during that process, they have to actually fill out a healthcare history.

Aneesh Chopra – White House – CTO
Yes.

Charles Kennedy – WellPoint – VP for Health IT

I would encourage us to look, not ignore the clinical implications of that process. We found that that's actually a pretty decent source of information that you may want to share with the physician or whatever, and getting consumer engaged is such a tough challenge. We really can't ignore any opportunity. So if there is an opportunity to leverage some of that information in the clinical direction, I'd encourage us not to ignore that.

Aneesh Chopra – White House – CTO
One of those policy questions, I think, is exactly what's the scope of what the state and federal exchanges will be. I think the question you're raising is, will the state and federal exchanges actually go to the point where that information is captured through the exchanges, or will that be passed on and captured at the individual vendors that they've chosen. Again, thankfully that's above my pay grade. That's the conversation to have with the team over at HHS designing the policy framework for how those are going to….

Charles Kennedy – WellPoint – VP for Health IT
Yes, that and not recreating the silos. I worry that we're just electronically recreating many of the silos we deal with today.

Aneesh Chopra – White House – CTO
In fact, we're asking – Anne Castro is on the standards committee from BlueCross BlueShield— specifically to help raise questions about, she did the exact same question you did. When we enroll people, here's the set of data that we collect. That may not be in the name, address, citizenship status, etc., and that's what I mean by inventory the cart base of data elements. I can't say that we know what all of them are going to be, and that all of them should be finalized that way, but at least we're going to inventory them, and I would encourage if you have not gotten that feedback, we get a message for the insurance industry can participate and has been very vocal.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Other questions or comments? I think this is a very exciting opportunity actually, I mean, to walk into a door, any door, and be able to understand who you are, what you're eligible for, the whole notification system. We talked about the outreach can go a long way to reducing disparities as another example, so this is very exciting.

Aneesh Chopra – White House – CTO
We are in service to this body and the standards committee so that I hope this is not a one-off visit. We'll keep you apprised as the stuff goes on and so that we can make sure we're course correcting, as you all provide feedback.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
That'd be wonderful.

Aneesh Chopra – White House – CTO
Thank you.

Gayle Harrell – Florida – Former State Legislator
May I add one more comment?

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Yes.

Gayle Harrell – Florida – Former State Legislator
I just want to make everyone aware when you go down the road to this all encompassing kind of system that, yes, gives you eligibly when you walk through one door and you have access to everything. It also, in the public perception, opens up the giant computer in the sky and big brother having access to you, so the privacy and security that goes along with this has to be incredible.

Aneesh Chopra – White House – CTO
Gayle, I will have failed if I've left you with the impression that there will be a single box to end all boxes, the one box to rule them all, in the Lord of the Rings analogy. There is no envisioned one box to rule them all. The question is, for any particular mini box, how might that mini box communicate such that if they were to find this kind of information out, each service call under the policy constraints that will be designed as part of the discussion here, that the method by which that information is transmitted and what it is to mean name, address, and so forth, that that be done in a manner that's standardized.

If I leave today with the impression that these guys are helping to give advice on a big box that will rule them all, I will have failed in my communication path. I hope I didn't fail that badly, but that scenario that you described, I would be hard pressed to imagine happening, a single thing that would rule them all. That would be very hard.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Latanya?

Latanya Sweeney – Laboratory for International Data Privacy – Director
Just a follow up, this is sort of … spirit of, it is exciting, and … is so contagious. But in the spirit of what Gayle was getting at, the other way to look at what she's saying though, I think you addressed her concerns immediately to … architecture, but … still … totally distributed situation where only the things that I normally collected, as my agency collects, I'm going to verify with the other, and you're just going to make that very efficient. The efficiency actually generates more mechanisms and ways that more things will automatically grow out of that, so you can still end up with the exact consequence of Gayle's concern, even though you didn't build it. It can be a perception problem.

Aneesh Chopra – White House – CTO
That's why in the testimony we had heard from the IRS, the design principle that they used for data sharing with the federal student loan form, the engineering of that was the IRS would not share that data directly with the Department of Education. You would have to log into the equivalent of the IRS system, and there's a button called transfer now, so you control if the data flows from the IRS into the FASA form, so you don't have to repeat all of those data elements. But in the design the IRS testified to, that's the control of the individual. And so that's a different design then saying, here. I'm going to sign off the authority for Latanya to go fishing, go find everything you can about me and go, good luck. Bring back my answers to all my problems.

That's why we had these discussions in terms of different models and how we're understanding the world, these various designs and architectures, such that this committee won't be recommending this, but will surface the tradeoffs, what are the privacy implications of choice A versus B? How can the data flow in a manner that is safe and secure in any of these scenarios? And I think that's a very likely conversation that we'll have over the course of the next few months is exactly this issue.

Is the IRS creating a higher risk environment or a low risk environment by relying on the individual to be the choice maker? If you gave me permission, do I take on more of a burden where big brother in the sky has all this information, that's exactly the conversation and all these scenarios, the policymakers will

have. At the end of the day, the key question is going to be how will the information move, and we will find a way in either scenario to learn what the least amount of overhead will be to do that and surface, I think, a very healthy conversation about whether the tradeoffs work based on the technical architectures for both scenarios. I've taken up my time.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Thank you very much, Aneesh. Look forward to seeing you in the future.

Aneesh Chopra – White House – CTO
Yes, sir.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
All right. Steve Posnack and Carol Bean are going to update us on the recently released rule on temporary certification.

Steve Posnack – ONC – Policy Analyst
I was actually going to thank you because this is the longest I've been out of the office in – I don't want to tell you. Just a little bit of history … I'm here with Carol Bean, and we are back again to tell you about the temporary certification program specifically, so a little bit of history. Early March, we published the notice of proposed rulemaking for both the temporary and permanent certification programs. We acknowledged that we were going to be finalizing the temporary certification program first, get that up and running. It's really the first kind of domino to set in the long string of dominos that we expect to fall into place. The comment period ended on April 9th, which was, if you do your smart calculation, about nine weeks ago, so we had a rule written, cleared, published in about nine weeks, give or take a few days, which is operating at the normal speed for ONC, right? Lightspeed for a lot of our efforts thought.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Are you working on meaningful use?

Steve Posnack – ONC – Policy Analyst
We are working just as fast with CMS. So it was an important day. The rule actually got published yesterday, so we celebrated its birthday yesterday. It was the first big step that will set into motion of the processes that needs to be in place, the certification of EHR technology. It also helps certain other ONC programs to kick into action. The regional extension centers can kind of start formulating their postures for how they're going to help the people that they want to get to meaningful use.

Generally speaking, just a quick reminder, the rule serves two purposes. It establishes the process for the National Coordinator to use to authorize organizations to test and certify electronic health record technology. It's an open process. We encourage all organizations that believe they're qualified to apply. And then the second purpose is that it sets the parameters around the testing and certification of EHR technology.

Once EHR technology is certified, it gets us one half of the equation, the certified EHR technology piece. That's part of the phrase meaningful use of certified EHR technology, so it's going to help provide confidence, provide assurance for the healthcare providers to seek to achieve meaningful use. The technical capabilities they need are going to be present in the EHR technology they adopt.

There's one person I need to thank that isn't here, and his name is Mike Lapinski, who is my right-hand man on staff to help write the rules, which is why we got it done so quick, so I'm not the only one that's writing the rules. It's really a group effort to get the rules out and do the briefings with David and other

leadership to really lock down all the policies before we start circulating the rules around. In the back of the rule, and I will attribute this to Mike, he meticulously kept track of all of the changes that we made, so there's really kind of a change order list of what were the differences between the temporary certification program proposals and what wound up in the final rule. That's towards the back, so if anyone has got the rule in front of them right now, they can turn to section four.

A couple of quick things that I wanted to call out in terms of the differences between the two rules that we got a lot, so I want to thank everyone that submitted a public comment. The input from the committee as well that we took into consideration, and that I hope you feel that we've embodied in a lot of the final rule policies, the first being the authorized testing and certification methods. We had proposed kind of a column A, column B approach where they had to offer, the ATCBs would have to offer testing and certification at their facility, and then let them choose several other methods as a secondary option. A lot of the feedback that we got back said they need to offer remote testing and certification, how that gets done. Leave it up to the markets to decide, but that's the primary focus that should happen first, so we went in that direction. We require that as a minimum option. Organizations with their business models, etc., can fly a team out I they want to, be there in person, but we don't require that.

The next is kind of two points that we picked up on, both from public comments and from your input as well. There are capabilities that must be present for certification, and those are related to the certification criteria adopted by the secretary, and then there are numerous other capabilities that healthcare providers will need in their just day-to-day operations. We are primarily concerned with making sure that the certification criteria that the secretary has adopted are embodied in the products and that they're certified as being there.

What we did is clarify that an ONC ATCB, authorized testing and certification body, must offer the option to just test and certify to the meaningful use supportive certification criteria. That's one distinction that we tried to make. You don't need to get certified to a broad range of other types of capabilities that HHS hasn't specified. Those could be additional services that a certification body would offer, but again, we don't require that as part of the program.

The other point that we brought up in terms of the final rule policy has to do with what we called inherited status. We got a lot of feedback on what happens if bugs, the EHR developer finds a bug or, as part of routine system maintenance, they create a new version? Whether it's version 1.1 from 1.0, or if they decide to move to the next major version release, as they're generally called, to 2.0. As long as the underlying capabilities that have been certified previously are still there, and they're not adversely affected by the changes, we allow the EHR developers to approach the certification body, provide an attestation that they haven't adversely affected the certified capabilities, and they would get, the next version would get an inherited certification. So it inherits the kind of parent's products that had been previously certified. That was one of the flexibilities that we tried to build in to keep pace with the market. We recognized that you can't just certify one version and expect it to be used for the remainder of the meaningful use cycle.

The last point that I just wanted to bring up, and this will dovetail in to some of Carol's statements, would be the transparency elements that we wanted to get across, so we had proposed that we would make available a certified HIT products list. The one stop shopping for anyone that wants to adopt certified EHR technology, we will be building out that Web page, the Web site where everyone can go to look at the products that have been certified, and they will specify certain information, including the version number, the date certified, the capabilities that they include, and we also required that, as part of issuing the certification, the EHR developers also communicate similar information to perspective purchases so that they know the capabilities that certified EHR technology will provide them. I'll turn it over to Carol.

Carol Bean – ONC

Thank you. I would like to start this by reminding you that one important reason that the ONC temporary certification program can provide this sort of assurance that Steve was talking about for providers and users to have confidence in the products is because this program is based on state of the art methodologies, best practices, and international standards that are used to determine the competency of entities performing the testing and certification that underlies that. In the temporary certification program, we have gotten – we've had a year to become very accustomed to the acronyms that we use, and they just sort of roll off our tongue, so try to identify these early and often.

In the temporary certification program, these entities that do the testing and certification are called ONC authorized testing and certification bodies, and we tend to refer to them as ATCBs. I'll try to identify those again when I use them, but I'd like to provide just a little information now highlighting what's coming next with respect to the timing on some of the more important milestones over the next couple of months. Yesterday, as the metaphor, this is a metaphor-laden day, was the date of birth of the program in terms of the rule going final and effective, so we are currently in the final, final stages of preparing the applications themselves. We're already receiving requests for applications.

As of yesterday, we had more than 30 requests for applications from entities who would like to apply to be authorized to do the testing and certification. Very few of those were what we call proper requests. We are the government, you know. They must request in writing with all the organizational contact information. As well, they must specify the scope of authorization that they are seeking. That is, whether complete or modular, to test and certify complete or modular, and if modular, which modules.

That will be important because the application itself consists of three components. The first component, of course, is instructions. Think about your IRS forms. It's not that bad. Part one is evidence of conformance to those international standards for testing and certification bodies and principles of proper conduct. Everybody who applies has the same part one. They have to provide all that information, and they must attest to the same things.

Part two of the application tests knowledge and competency with respect to HIT, health information technology, the standards and certification criteria that were adopted, and the testing tools, methods, and procedures. Part one is the same for everybody, but part two because, if you think about it, if people are seeking authorization to test and certify different kinds of things, then we want to be able to tailor the test to the scope of authorizations sought. Just as information, application parts one and two may be submitted separately, but an application is not complete until all components of both parts are in our hands.

On July 1st, ONC will begin accepting applications from these entities seeking authorization to test and certify under the program. July 1st, that's next week, to become ATCBs. Once their application is complete, we are committed to providing a decision to authorize or not within 30 days. All applications will be reviewed by the same panel, an internal application review board. They must be successful on part one, which essentially is a quality conformance assessment to the standards and quality assessment before they move to part two, which essentially is the technical, testing the technical competency. And once authorized, a list of all authorized ATCBs will be provided on the ONC Web site.

We expect by late summer, no later than late summer that there will be operational ATCBs, and once they are authorized, they will work directly with vendors, developers, etc. and others who are seeking to have products or technologies certified to do that. They report, the ATCBs report the certified products and information about those and what they're certified to, all the specific criteria to us, and coming full

circle, we publish. We aggregate that information and publish that on the CHITPL, the certified HIT products list.

That's a new acronym to remember, the CHITPL, always holy on the CHITPL. The CHITPL is conceived of as essentially a public service Web site to aggregate those lists of certified products and technologies, as provided by the individual ATCBs. In addition, the CHITPL can provide, upon request, a single number that would be used for meaningful use reporting to CMS. We've got a lot of work ahead of us. We've got a lot of work behind us, and the fun begins, so thank you.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Thank you. Comments, questions, David?

David Bates - Brigham and Women's Hospital - Chief, Div. Internal Medicine
Can I just ask, do you have a sense for how long the period is likely to be open and whether you have any…? It starts July 1st. Is there some time that it is going to end?

Carol Bean – ONC
We will accept allocations throughout the entire lifespan of the temporary program. Obviously entities that get their applications in and receive authorization sooner can begin work sooner.

David Bates - Brigham and Women's Hospital - Chief, Div. Internal Medicine
Do you have any sense of how many programs you're aiming for?

Carol Bean – ONC
We're aiming for the more the merrier. It's wide open. We have no limit on applicants, and we have no limit on authorized bodies. As I said before, we always have 30 requests for applications. Obviously I don't think that's going to translate into 30 ATCBs, authorized testing and certification bodies, down the road. But from public comments, from public announcements, we believe we're very confident that there will be multiple bodies testing complete EHRs, as well as multiple bodies testing various modules.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Any other questions? Paul?

Paul Egerman – eScription – CEO
Yes. I was just going to say, first, it was a great presentation. Having worked on this with Marc Probst and a lot of other people, it's gratifying to see that you did, that our recommendations did have an influence on what you did, so I thought that, and it's a very complicated area. You did a terrific job, and I appreciate, especially like the whole one stop shopping approach, the idea that you have that runs the federal database that people can look to. I think that'll be very important.

I am, have to say, Carol, surprised by the number of 30 applications. That's more than I would have predicted. I guess you too, but … we'll end up with more than one testing facility I think is also excellent for the industry, so this is a good step forward. This is actually the first thing that we've taken all the way through the entire rulemaking process, and so this is great.

Steve Posnack – ONC – Policy Analyst
Yes. I think we're really encouraged by, I mean, what Carol said that we set up a process that it's not a cake walk to get to be an authorized testing and certification body, but those that come out of the process will be qualified according to the standards, but we're really encouraged by the amount of interest in it.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Any other comments? Congratulations. ONC and CMS, HHS has really been impressive in the past year and a half it's been since the change in administration, and so much has come out.

Steve Posnack – ONC – Policy Analyst
You have a lot of stuff on your summer reading list.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Yes. Right.

Steve Posnack – ONC – Policy Analyst
Thank you.

Carol Bean – ONC
Thank you.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Thank you.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
We now are ready for the public comments, I believe.

Judy Sparrow – Office of the National Coordinator – Executive Director
If anybody in the audience cares to make a comment, if you would just come up to the microphone, which I think Joe is putting up, or you could use one of the microphones here at the table. The operator will now tell us how to dial into the meeting for a comment if you're on the computer or on the telephone. Operator?

Operator
(Instructions given.)

Judy Sparrow – Office of the National Coordinator – Executive Director
We do have one caller on the phone. Could you please identify yourselves, your name, your organization? And the comments are limited to three minutes. Thank you.

Operator
Mr. Segal, your line is live.

Mark Segal – GE Healthcare – Director Government & Industry Affairs
Yes. Thank you. This is Mark Segal from GE Healthcare, and I just wanted to make a quick comment relative to the certification process final rule. We're still reviewing the content, but I'd like to express appreciation for the excellent work that was done. Many of our priority points were very positively addressed in those comments, so thank you for that. The observation I wanted to make, and it relates to some of the timing issues that were discussed earlier in the context of the NHIN Direct, there were a couple of statements about timing for certification, looking ahead in the certification process final rule that I'd like to ask be given careful consideration, as you move forward.

There was an expectation where ONC said they expect that they anticipated that testing and certification for the 2013, 2014 period would need to begin by mid 2012, and concerned about that given that obviously the next stage of meaningful use would begin in October 2012 for hospitals. That seems late.

Likewise, and slightly inconsistently, there was an expectation that ONC set out that the next set of standards and certification criteria would be published in late summer 2012, again rather late. And so we certainly recognize the need for ONC and for the policy committee to balance the need for feedback from state one with the need to get early meaningful use criteria for providers and certification criteria for providers and vendors. I know that the policy committee had addressed this acting on a recommendation from the adoption and certification workgroup on patient safety talking about the need for criteria 18 months in advance of when they're needed. So I'd just ask that these dates, which were put in as projections, be carefully looked at to make sure that both providers and vendors have what we need early for safe and effective implementations and development of the next stage of EHR technology. Thank you.

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you, Mr. Segal. There are no more comments on the phone, Dr. Tang.

Paul Tang - Palo Alto Medical Foundation - Internist, VP & CMIO
Thank you, everyone, for another meeting, and look forward to July when I believe Paul Egerman promised to solve all the … issues … C and D. Take care. See you next month.

Public Comment Received During the Meeting

1. Will you be able to authorize testing & certification bodies prior to the final rule for MU?